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Lifestyle Medicine: An Overview

The recent debate on health care reform has highlighted the increasing burden of the cost of chronic disease and the lack of effective means to address these challenges. Lifestyle medicine traditionally has been embraced by primary care physicians, but until recently there have been obstacles for dissemination due to poor or absent reimbursement, questions regarding the efficacy of interventions, and the sheer volume of acute episodic medical care that squeezes our time with patients.

—The Editor

Definitions/Differentiation

Lifestyle medicine is an evolving approach to patient care that focuses on comprehensive, evidence-based health assessment and natural treatment approaches. Although the use of the term "lifestyle medicine" is new, in many ways the practice of lifestyle medicine returns the health care provider to core health care concepts that have been in existence for years, but have recently gained increasingly large bodies of scientific evidence supporting their practice.

There are many definitions of lifestyle medicine. The broadest-based denotation states, "Lifestyle medicine is the evidence-based practice of helping individuals and families adopt and sustain healthy behaviors that affect health and quality of life. Examples of target patient behaviors include but are not limited to eliminating tobacco use, improving diet, increasing physical activity, and moderating alcohol consumption."[1] Lifestyle medicine includes a thorough assessment of an individual's current health habits, development of individualized treatment plans, and implementation of individual, group, and community resources that assist in health behavior change. Lifestyle medicine approaches can be used in primary, secondary, and tertiary prevention arenas — it can prevent the development of disease risk factors, modify risk factors when they are already present, and treat disease if risk factors have progressed to that level. Lifestyle medicine focuses on recognizing and treating the causes of disease, not just the symptoms.[2]

Most lifestyle medicine definitions refer to the use of lifestyle interventions in the prevention and treatment of chronic disease. Lifestyle interventions are generally considered to be activities that are a common part of the human condition but are frequently not practiced in the manner that is known to maximize health. The most common of these lifestyle interventions is the proper use of food and nutrition. How an individual eats and takes in nutrients can greatly affect his or her health both on a short- and long-term basis. Interventions by health care providers that improve diet and nutrition should be foundational to much of both acute and chronic care. The second most frequently mentioned lifestyle intervention is physical activity. Evidence that increased physical activity improves health and well being is strong. Health care providers can influence participation in physical activity, thereby strengthening an individual's health status. Other lifestyle factors that are frequently mentioned include rest and

Executive Summary

- The majority of our health care resources are devoted to surgery and medications rather than preventive medicine.
- The U.S. overall cost of unhealthy lifestyles has been estimated to reach $100-150 billion annually.
- The consensus conference on lifestyle medicine has recommended 15 competencies that all PCPs should possess.
- Lifestyle prescriptions for diet and exercise can be hard-wired as easily as they are for medications and treatments.
- Outpatient billing for lifestyle medicine is addressed in the health care reform legislation and with Medicare.

proper sleep as well as the development of stress management tools including balanced social, emotional, and spiritual support systems. Finally, at times individuals make choices that are detrimental to their health, such as smoking or drinking too much alcohol. In these cases, lifestyle interventions are focused on assisting individuals in removing these exposures. Classic examples of these types of interventions are smoking cessation counseling and limiting alcohol use to moderate levels.

Lifestyle medicine is not complementary or alternative medicine. It is based on strong evidence for the value of lifestyle interventions in a variety of disease states. It does not bring experimental or unproven approaches to health and is, in fact, core to most nationally recognized protocols for the treatment of diabetes, hyperlipidemia, hypertension, and a variety of other disease states. While lifestyle medicine supports the proper use of other preventive measures like immunizations and chemoprophylaxis or integrative therapies such as judicious herbals, massage, and energy techniques, these are not considered lifestyle medicine because they go beyond the simple, natural approaches discussed above that form the core of lifestyle medicine. The relationship of lifestyle medicine to other aspects of health care can be seen in the context of a hierarchal treatment triangle. (*See Figure 1.*)

Currently, the majority of our health care resources go toward the top ends of this triangle. Lifestyle medicine practitioners believe that it should be the other way. Lifestyle practices and health habits are among the nation's most important health determinants. Changing unhealthy behaviors is foundational to medical care, disease prevention, and health promotion. While lifestyle medicine does require a certain knowledge base and skill set, it is much more than that — it is really a philosophy and approach to care that is rooted in the science of conventional medicine but goes beyond traditional medical training.

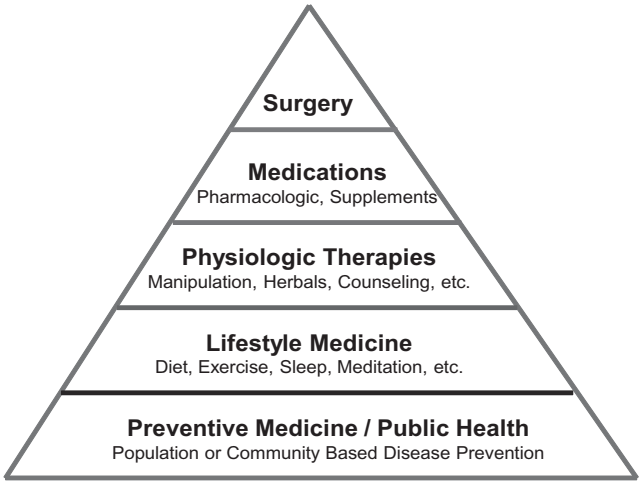
History/Background

Lifestyle medicine — adjusting nutrition, physical activity, and rest to maximize health — has existed since the first time a human felt unwell. Around 400 B.C., Hippocrates summarized health and healing, stating, "the natural force within each one of us is the greatest force in getting well. Our food should be our medicine, our medicine should be our food … food and exercise … work together to produce health."[3] More than 2000 years later, these concepts were still dominant when Thomas Edison hypothesized, "the doctor of the future will give no medicine, but will instruct his patient in the care of the human frame, in diet and the cause and prevention of disease."

The modern age of lifestyle medicine really began with the publication of a lifestyle medicine text in 1999.[4] A Medline search for articles mentioning lifestyle medicine in 1998, the year prior to the text publication, found 669 articles. By 2008, the number of articles mentioning lifestyle medicine had almost quadrupled to 2284 articles. In 2004, a lifestyle medicine professional association, the American College of Lifestyle Medicine, was formed.[5] The first formal lifestyle medicine training program was started by Loma Linda University in 2006.[6] This was followed in 2007 by the first peer-reviewed professional journal dedicated to lifestyle medicine, the *American Journal of Lifestyle Medicine*.[7] In 2008, a second Lifestyle Medicine text was published.[8] In 2009, a consensus conference on lifestyle medicine was facilitated by the American College of Preventive Medicine. This important meeting brought together physicians from the American Medical Association, the American College of Physicians, the American Academy of Family Physicians, the American Academy of Pediatrics, and several other specialty societies with the express purpose of developing a set of lifestyle medicine competencies that should be adopted by all primary care physicians. Institutes for lifestyle medicine now exist at Harvard Medical School and Loma Linda University.

The greatest force behind this rapid expansion of interest in and resources for lifestyle medicine has been the epidemic of chronic disease, especially diabetes mellitus type 2 and obesity. In the past 100 years new methods for growing, processing, shipping, and storing food has led to a dramatically different set of nutritional choices. At the same time, the development of modern transportation and communication systems has disincentivized physical activity. These environmental changes have dramatically affected caloric balance, sparking a crippling wave of morbidity and early mortality — first in the developed world, and now increasingly in the developing world. Modern technologies and environmental changes have not only reduced activity and led to

Figure 1: Treatment Triangle



Adapted from Complete Healthcare Model, © 2005 Marc Braman, MD, MPH.

the consumption of more food that is less healthy, they have also led to a more rushed and stressed society that is less able to find adequate rest, sleep, and social and spiritual support systems.

Current Status

Currently, the average American does not practice what is known to be healthy. Eighty percent need to significantly improve their nutritional status,[9,10] and three-quarters don't get adequate physical activity.[11] Close to one-third get significantly less sleep than is ideal,[12] and only one in 33 achieve ideal nutrition, physical activity, weight, and smoking status.[13] The inability to practice healthy lifestyles has led to a well-documented epidemic of chronic disease. Two-thirds of the American population are either overweight or obese.[14] One-third are pre-diabetic and more than one-eighth have a diagnosis of diabetes.[15] More than half of individuals older than age 60 have metabolic syndrome,[16] and two-thirds of those older than 65 have hypertension.[17] Many individuals who have these diseases don't realize they have them,[18] and even those who do recognize it frequently do not implement the lifestyle choices that are available to achieve adequate disease control and/or reversal.

The burden of chronic disease has placed an enormous strain on the American health care system. It is now estimated that up to 80% of the care provided by primary care physicians involves treatment of diseases that should first be addressed by improving lifestyle choices. The overall cost to the U.S. health care system of unhealthy lifestyles is difficult to quantify but has been estimated at $1.3 trillion each year.[19] Assisting the average American in implementing healthier lifestyle choices is recognized as a major challenge by both the medical community and policy makers. Exactly how to do this is more controversial. Population-based interventions such as food labeling and changing the built environment are important and discussed elsewhere.[20] There is also a place, however, for improved individualized counseling by physicians and other health care professionals. Both population and individual approaches to improving lifestyles have been incentivized in the Patient Protection and Affordable Care Act of 2010.

The body of evidence for the value of lifestyle change is enormous and, for the most part, not disputed. A high-level overview of this literature is provided in the effectiveness section of this paper. An understanding of the efficacy of health behavior change and the ability for a physician or other health care provider to successfully implement clinically significant changes for individual patients is more controversial. The evidence for the value of this is nonetheless still strong and is reviewed in the health behavior change and approaches sections of this paper. Most physicians would not argue against the value of lifestyle change, the ability of individuals to change, or the importance of their role in facilitating this change. When studied, however, the majority of health care providers do not routinely screen nor adequately assist patients in modifying their health-damaging behaviors.[21-23] The current challenge for the health care delivery system is no longer proving that lifestyle interventions work, but rather in enhancing clinicians' and the health care system's commitment to learning how to incorporate the interventions into their practices and to deliver specific, compelling messages and strategies to patients.[24]

The reasons why inadequate implementation of individualized therapeutic lifestyle changes occurs are multi-factorial but fall into two major categories. The first is logistical: time constraints and lack of reimbursement incentives. This will be discussed in the practice section of this paper. The second major reason solid lifestyle medicine is poorly implement is directly connected to inadequate medical education and the resulting poor self-efficacy in this area.[25] It is common for physicians to admit to poor training and lack of confidence in implementing lifestyle changes.[26,27] This is especially true when it comes to obesity care.[28] Addressing the education and self-efficacy issues is the major thrust of this paper.

Practice Patterns

From a lifestyle medicine perspective, there are three significant concerns around how the typical physician approaches chronic disease care. The first is initial identification of the value of a therapeutic lifestyle change for a particular patient with a diagnosed disease. The majority of physicians do not routinely screen

Table 1: Lifestyle Medicine Assessment for Health Behavior Change

Health Habits Assessment	Core Beliefs and Efficacies
Nutrition	Locus of Control
Physical Activity	Personality Type
Rest/Renewal	Learning Style
	Preferred Processes of Changel
Previous Lifestyle Change Efforts	
Type of Program	**Readiness for Change**
Success of Program	Identification of stage
Support System Availability and Use	Recycling
Enjoyment	Termination
Environmental Contexts	
	Barriers and Resources
	Financial
	Logistical
	Human
	Education/knowledge

for lifestyle activities and change opportunities in patients who have ongoing disease states. Despite the prevalence of chronic maladies, the National Health Interview Survey (NHIS) has found that less than one-fourth of patients report having ever received any nutrition or physical activity counseling from their physician.[29] Especially problematic is the under-recognition by physicians of the importance of weight loss in disease prevention and treatment. Only two in five obese patients receive any advice to lose weight, even when they have chronic diseases that are clearly worsened by their obesity.[30,31] So, the first problem the typical physician deals with is consistently recognizing that therapeutic lifestyle change is the treatment of choice for the patient in front of him or her.

The second improvement opportunity for the typical primary care physician relates to the fact that even when the average health care provider clearly recognizes that a particular patient would benefit from a significant change in lifestyle, he or she frequently doesn't fully advise the patient on either medical issues or specific concerns. Even those with known lifestyle-related diseases such as diabetes, hypertension, and hyperlipidemia received counseling only 30-45% of the time. The likelihood of receiving lifestyle modification advice decreases with age, for women, and for established patients.[32,33] No more than 25% of patients who do receive counseling around weight loss are provided specific advice on dietary fat or physical activity.[34,35] Patients are especially unsatisfied with what and how the health care provider approaches weight loss compared to health care in general.[36] In one study, only half of those with weight problems reported receiving specific weight-loss strategies, and three-quarters of these had little confidence in the ability of their physician to give useful advice.[37]

The third lifestyle medicine concern is that even when patients who could benefit from a therapeutic lifestyle change are adequately screened, identified, and given focused advice on health behavior change, they are not given adequate tools with which to implement their healthy behavior goals. Physicians must move beyond the tendency to give simple advice. A brief educational exchange is most commonly not enough to produce sustained behavior change.[38] Development of a personalized lifestyle change plan that includes specific lifestyle medicine prescriptions, team support, and the use of community resources needs to be incorporated into all chronic disease care.

Physicians need to: 1) recognize that the health issues faced by the average person with chronic disease are lifestyle related; 2) consistently address these lifestyle issues as a foundational component to their patient care encounters; and 3) provide their patients with not just advice but a whole tool kit that will maximize their resources as they go about instituting healthier lifestyles.

Lifestyle Medicine Competencies

The health care provider can and should have a strong and positive role in addressing and implementing lifestyle change. The knowledge and skill required to do this includes a lifestyle assessment, adequate understanding of behavior change, and implementation of both individual and team or community resources to assist in behavior change. Although many health care providers do not feel well trained, the value of physician counseling and interventions for health behavior change is well documented. This has been most broadly seen in smoking cessation,[39] but is also clearly important in nutrition and physical activity counseling.[40]

The United States Preventive Services Task Force (USPSTF) recommends that physicians screen all adults for obesity, tobacco, and alcohol use. They also advocate intensive counseling and behavioral change interventions for weight loss for those who are obese, and dietary changes for all who have hyperlipidemia or other known risk factors for cardiovascular and other chronic diseases that are affected by nutritional status.[41] The American Medical Association (AMA) has stated that physicians have a key responsibility to promote preventive measures and encourage positive lifestyle behaviors for those who are obese. This includes counseling and work with effective weight management programs.[42]

The consensus conference on lifestyle medicine has recommended 15 lifestyle medicine competencies that

all primary care physicians should have.[1] These competencies include recognition of the literature documenting the connection between lifestyle change and health outcomes and the science behind health behavior change, as well as the ability to perform comprehensive lifestyle assessments including predispositions and readiness to change. To implement lifestyle change, physicians should know how to establish effective relationships and use national guidelines. They also need to understand the value of lifestyle medicine prescriptions and be able to use team approaches, referrals, and medical information technology to maximize lifestyle medicine care. Physicians should promote healthy behaviors as the foundation of health promotion and medical care as well as personally practice a healthy lifestyle.

Health Behavior Change

Successful health behavior change is the cornerstone to implementing lifestyle medicine in the individual or group patient care encounter. Changing a health behavior requires an understanding of current status including patient readiness to change; a patient encounter that leads to positive patient motivation for change; and implementation of ongoing support resources for sustained healthier lifestyles. The 5As (ask, advise, agree, assist, arrange) health behavior change framework has been successfully implemented in smoking cessation and, with modifications, holds promise for multiple facets of lifestyle medicine.[43]

Health behavior change will not occur unless the physician knows the patient well. Knowing a patient well includes understanding his or her current health habits. This includes a clear understanding of existing nutrition, physical activity, and rest patterns; a trends analysis reviewing previous lifestyle change efforts focusing on successes and failures; a specific readiness to change analysis; an assessment of core patient beliefs and efficacies, including likes and dislikes; and an overview of barriers and resources the patient will encounter and/or need in the path toward a healthier lifestyle.[44] (*See Table 1.*)

Much of this information gathering is best accomplished in a longer initial patient encounter. Incorporation of a "health habits" section to the medical record that is completed by either the patient, provider, or a trained staff member is crucial. Implementation of a computerized health risk assessment tool also can be very valuable.

A positive patient encounter that sets a motivated foundation for change is also critical for development of improved health behaviors. For this to occur, each and every provider-patient interaction must be based on an underpinning of respect and curiosity. Such encounters begin by developing the ability to listen to the patient from an empathetic perspective[45] and continue with appreciating a clear understanding of what motivates, inspires, and creates meaning for that individual. This requires the ability to roll with the resistance that commonly occurs with initial exposures to recommended change and resist the desire to force patients down the "right" or provider-preferred change path. In this process, patients must be helped to see the discrepancies that exist between their stated or envisioned life goals and their actual current life situation. Throughout the patient encounter, the provider must consciously seek to empower the patient by infusing hope and optimism. These concepts, referred to as motivational interviewing, can be developed through training and practice.[46]

There are two important support resources, one from the medical community and one from the behavioral health community, that are important for successful early and sustained lifestyle change. For early lifestyle change, implementation of a lifestyle medicine prescription system encourages small, concrete health behavior change steps. A lifestyle medicine prescription, or lifescription, begins with medical prescription concepts that require written medication guidelines from the health care provider to the pharmacist (and on to the patient). These prescriptions are highlighted by three characteristics: individuality, clarity, and brevity. The details of these prescriptions for particular interventions are discussed in the next section of this paper. They have been documented as valuable primarily in the physical activity realm,[47] but show great promise for nutrition, rest, and other lifestyle medicine interventions.

Another important lifestyle medicine resource for ensuring sustained lifestyle change is the support group. The value of an open, honest group of caring and empathetic individuals who encourage accountability and positive change has been most clearly demonstrated in the addiction world. Alcoholics Anonymous is perhaps the most successful health behavior change program ever. Since it is common to the point of being considered the norm for people to choose an unhealthy behavior even in the face of negative consequences, all patients dealing with lifestyle-related chronic disease should be encouraged to develop a support system, ideally a small group but minimally an individual. The use of interactive technologies as a support system is a growing field that also shows tremendous potential for supporting healthy lifestyle choices.

Lifestyle Medicine Interventions

Lifestyle medicine interventions can be disease-focused or risk factor-focused. This paper provides a brief overview of both approaches. As a general rule, however, a risk factor-focused approach to changing lifestyle is encouraged. There is good evidence that the same healthy behaviors positively affect the majority of chronic diseases. The same small, incremental change can improve obesity, diabetes, hyperlipidemia, hypertension, arthritis, and a host of other disease processes. For the primary care practitioner, developing knowledge, skills, and tools for assisting patients in healthier nutrition, increased physical activity, balanced rest, and other

Table 2: Examples of Nutrition Support Groups

12-Step Groups
• Overeaters Anonymous (OA)
• Compulsive Eaters Anonymous
Commercial Groups
• TOPS (Take Off Pounds Sensibly)
• Weight Watchers
On-Line
• MyDietBuddy.com
• Weightcircles.com

improved lifestyles can be used in multiple disease states and settings. As discussed above, implementing a comprehensive health habits assessment is the critical first step in all risk factor focused approaches to lifestyle change. Once the assessment data are obtained, there are some key considerations for each of the core lifestyle interventions.

Nutrition. An understanding of nutrition is foundational for the health care provider who practices lifestyle medicine. The scope of this article does not allow a detailed review of nutritional principles as they relate to improved health. Instead, we will briefly touch on two basic nutrition themes and then review some key guidelines for approaching patients who could benefit from an improved nutritional status.

What appears to be the greatest challenge in the area of nutrition is clarity on what is the optimal diet. When a high-level overview is taken, however, recommendations from numerous national organizations create a common set of themes.[48-50] The first is an emphasis on whole foods. Whole foods are best described as food that is consumed fresh, in its natural state. Any movement toward slicing, grinding, or preserving starts food down the processing pathway. Further, processing may include extracting certain portions of the food or adding manufactured coloring, flavoring, or texturizing. These steps change the context with which nutrients enter the body, decreasing their biochemical value. Classic whole foods that are readily available, economical, and clearly beneficial to health include all varieties of vegetables, fruits, and legumes. The average American does not get even the minimum recommendation of 5 servings of fruits and vegetables per day,[51] and the value of the fiber and plant protein content of legumes is highly under-recognized and under-utilized.

The corollary to increasing whole foods is decreasing processed foods. There are four food components that are frequently highly processed and dramatically overused in the standard American diet. These are salt, sugar, saturated fats, and grains.[52] There are three primary sources of extra salt: snack and fast foods, canned foods, and added salt. Unneeded sugar also is commonly found in snack and fast foods as well as desserts. Sugar is the most common ingredient in liquid calories from sodas to juices to coffee and tea. It also is frequently connected to grain products such as cereals, muffins, and certain breads. Extra saturated fat tends to come from animal products. The saturated fat content of red meats has been highly publicized. What is less known is how much saturated fat is in cheese. (A cheeseburger has 50% more saturated fat than a hamburger — the difference being the cheese.) Processed wheat, corn, and rice account for more than 50% of the calories in the standard American diet. These show up in many types of packages in convenience and grocery stores in forms such as pastries, cereals, crackers, breads, and many types of chips.

It is difficult to find a patient who consumes enough whole food, and even harder to fine one who doesn't use any type of processed food. This makes a lifestyle nutritional intervention beneficial for close to every patient encounter. Assuming the proper lifestyle assessment and motivational interviewing techniques are applied, the next step in a nutritional intervention should be to provide brief counseling and create a customized nutrition prescription for the patient. One formula for creating a nutrition prescription focuses on reversing fat by using TAF (type, amount, and frequency) as a guideline. Nutrition prescriptions can be positive (i.e., eat more of) or negative (eat less of), should be small steps forward, and must be seen as attainable by the patient.

There are many opportunities for support groups around nutrition. A partial list is given in Table 2.

Physical Activity. The ideal standards for physical activity recommendations are clearer than the ideals for nutrition. The basic guidelines are listed in Table 3.[53]

Moderate-intensity physical activity means working hard enough to raise your heart rate and break a sweat, yet still being able to carry on a conversation. This recommendation is for the average healthy adult to maintain health and reduce the risk for chronic disease.

Like nutrition, there is much room for improvement in physical activity for the average American. Exercise prescriptions frequently follow the FITT (**f**requency, **i**ntensity, **t**ime, **t**ype) formula. A more exact way to calculate intensity is by calculating a training heart rate using the following formula: Training heart rate = Maximum heart rate (220 - age) x 0.6 to 0.85.

The value of physical activity goes beyond traditional exercise programs. Incorporating movement such as walking and stair climbing into activities of daily living and involvement in recreational pursuits that require exertion also provide long-term health benefits. Patients who have negative perceptions of exercise may be more open to physical activity prescriptions that incorporate atypical movement endeavors. A key physical activity resource is the Exercise Is Medicine web site and associated resources.[54] Physical activity support systems can be found among friends and co-workers, in exercise groups such as running clubs, and in commercial programs

Table 3: Physical Activity Guidelines[53]

Moderately intense cardio 30 minutes per day, 5 days per week
OR
Vigorously intense cardio 20 minutes per day, 3 days per week
AND
8-10 strength training exercises, 8-12 repetitions of each, 2 days per week

Other Hints:

- **Get a variety of types and/or locations**
- **Do something you think is fun**
- **Use a support system if possible**

such as Curves.

Rest. The core rest recommendation is 7-8 hours of sleep each night.[55] Individuals who are able to incorporate naps or siestas into their daily life[56] as well as meditation and relaxation techniques have decreased morbidity and mortality.[57] Inclusion of sleep and self-care as a component of a health habit questionnaire brings significant insights into a patient's stress and coping mechanisms. Because stress reactions are so closely related to sleep patterns, lifestyle prescriptions for increased meditation and relaxation techniques are the initial treatment of choice for insomnia.[58] Incorporation of rest and renewal into a patient's daily life frequently requires an understanding of a patient's spiritual resources and perspective on life.

Other Lifestyle Interventions. Nutrition, physical activity, and rest prescriptions are the most common lifestyle interventions. Modifications of numerous other basic approaches to living also can be beneficial. Elimination of substance abuse is an important area. Cigarette smoking continues to be one of the greatest killers in the United States. Simple office-based interventions can be very helpful in smoking cessation. Abuse of alcohol and prescription and illegal drugs also can lead to serious health consequences. Treatment of these issues frequently requires a more intensive therapeutic intervention. Fully exploring the value of social and spiritual support systems and prescriptions for improving these is beyond the scope of this paper. A holistic approach to health care, however, requires a recognition of the need for balance in all aspects of life.

The Effectiveness of Lifestyle Medicine in Treating Chronic Disease

Healthy lifestyles are recommended in virtually every practice guideline for chronic disease prevention and treatment. Key examples of the evidence supporting these approaches is summarized in core recommended approaches to obesity[59] and metabolic syndrome[60] as well as guidelines for the treatment of diabetes,[61] hyperlipidemia,[62] and hypertension.[63] Further details of these recommendations follow.

Obesity. Although there is a place for medications and surgery in obesity treatment, the most important component of all weight loss, and the portion applicable to a typical primary care office, is lifestyle based. Weight loss is best achieved with a combination of improved nutrition and increased physical activity. Moderate and well-balanced calorie restriction is more effective than any specific diet. A caloric deficit of about 500 kcals per day is equivalent to one pound of weight loss per week and is the optimal goal for most.[64] Movement toward a moderate, well-balanced eating pattern can be facilitated by focused, small-step improvements. One of the best tools for successful adoption of these small steps is the nutrition prescription. Considerations when creating nutrition prescriptions for those who are obese include a recognition of the value of increasing fiber and legumes and decreasing refined grain products and fats.[65] Encouraging smaller, more frequent meals also is effective.[66] Exercise is not as effective as diet in producing caloric deficits, but is valuable in weight loss maintenance.[67] The most successful lifestyle interventions for obesity incorporate not only improved nutrition and increased physical activity, but also address emotional and social issues, taking advantage of counseling and support systems.[68]

Diabetes. Diabetes type 1 and type 2 are distinctly different physiologic processes. Lifestyle interventions can assist with both but are the core treatment for type 2 diabetes mellitus. Patients at risk for diabetes and those with early issues with hyperglycemia should know that their risks, and in fact the whole disease process, can not only be stopped but actually reversed by adopting healthier lifestyles.[69] There is no other viable treatment alternative.[70] The current epidemic of diabetes, pre-diabetes, and metabolic syndrome should by itself be enough of a stimulus for the primary care practitioner to ensure his or her practice has adequate lifestyle medicine resources. The lifestyle interventions that are most successful in diabetes type 2 prevention and treatment are similar to those already reviewed above. Core guidelines include an emphasis on caloric deficit to promote weight loss, generous use of whole foods — especially legumes and other high-fiber plant products, and decreased total protein intake ensured by decreased use of animal products.[71]

Hyperlipidemia. Lifestyle interventions are recommended as the first-line treatment for elevated cholesterol and dyslipidemia. Specific lifestyle improvements that work include decreased saturated and trans fats, decreased cholesterol, and increased dietary fiber and physical activity.[72] Primary care practitioners anxious to assist hyperlipidemic patients with lifestyle interventions prior to or in addition to medications

should be comfortable in prescribing specific nutrition prescriptions that either dramatically decrease or eliminate trans fats, saturated fats, and cholesterol in the diet. Since cholesterol is an animal product, an easy although sometimes poorly tolerated prescription is to eliminate the intake of animal products. The more important food component to focus on in reversing hyperlipidemia is saturated fats.[73] A low saturated fat diet combined with increased fiber can lower cholesterol levels as much as a statin.[74] In studies where dyslipidemia and actual atherosclerosis have been successfully treated and in fact reversed using aggressive lifestyle interventions, saturated fats were eliminated and total fat intake was lowered to 10% of all calories.[75] A community-based intervention, the Coronary Health Improvement Project (CHIP), is the best documented support group for treating hyperlipidemia and reversing heart disease.[76]

Hypertension. Therapeutic lifestyle interventions are recommended as the first-line treatment, prior to medications, for patients with hypertension. Again, implemented properly, they can be as powerful as medication. The core lifestyle interventions discussed above work to decrease high blood pressure; however, there are some specific focus areas to consider when applying lifestyle medicine approaches to the hypertensive patient. The first is salt restriction. Sodium intake should be lowered to no more than 100 mmol/day and ideally to 50 mmol/day.[77] (Mmol x 23 = mg, so this is equivalent to a 1-2 g sodium/day diet.) The second lifestyle intervention that has more evidence for hypertension than other chronic diseases is stress reduction. Prescribing specific meditation techniques and/or relaxation therapies statistically lowers both systolic and diastolic pressures at a level equivalent to many medications.[78] A third area for evidence-based lifestyle medicine approaches to hypertension is substance abuse. There are clear correlations between both cigarette smoking[79] and alcohol abuse[80] and high blood pressure.

Other Chronic Diseases. The scope of this paper does not allow a review of the literature for lifestyle medicine approaches to other chronic diseases. There is a solid evidence base available, however, for the value of lifestyle interventions in a wide variety of disease states. These include stroke, heart failure, chronic obstructive pulmonary disease, osteoarthritis, rheumatoid arthritis, low back pain, prostate cancer, breast cancer, fibromyalgia, chronic fatigue syndrome, and depression. The type and dosing of the beneficial lifestyle interventions vary somewhat from disease state to disease state, but the core principles of increasing whole foods, decreasing processed foods, increasing aerobic and strength-building physical activity, increasing rest and relaxation techniques, and decreasing smoking and substance abuse consistently hold true.

Lifestyle Medicine Reimbursement

Currently, the majority of lifestyle medicine practice is reimbursed using typical office visit billing procedures. Patients present with a symptom set or one or more chronic disease diagnoses. They are evaluated and treated as any typical patient, but instead of a medication prescription they are given a lifestyle prescription and/or other lifestyle intervention. Because lifestyle medicine incorporates large amounts of health behavior change, and this frequently requires counseling and education, providers should consider billing using time instead of trying to meet the typical requirements around history, physical exam, and visit complexity. Time codes are listed in Table 4.

Specific lifestyle-related billing codes do exist for particular disease or risk states as well as for certain defined treatment activities. Examples include nutrition counseling for diabetics, nicotine cessation counseling for smokers, and exercise and nutrition therapies for patients undergoing cardiac rehabilitation. Despite these reimbursable treatment opportunities, the majority of primary care offices will find that billing using more traditional techniques and codes is simpler and economically smarter in the long term.

The health care system reform legislation signed in to law in March 2010 includes several specific supports to lifestyle medicine. An annual wellness exam that is exempt from co-payments and deductibles is encouraged. These will include coverage for all preventive services recommended by the United States Preventive Services Taskforce. The wellness exam is covered by Medicare beginning in January 2011, is incentivized for Medicaid, and is also required for private insurers. Individuals seeking preventive care services are well positioned for lifestyle interventions. Other provisions include demonstration programs to develop the concept of the individual wellness plan for at-risk individuals in federally qualified health centers, and support for employer-based wellness programs.

The real reimbursement incentives for lifestyle medicine will come as outcomes-based reimbursement is implemented. Although they may require a significant time and support system investment, when compared to most pharamacologic and interventional treatments, lifestyle medicine approaches to health care are inexpensive and cost effective. The concept of reimbursing health care providers for patient outcomes rather than for specific visits and/or procedures will reinforce the value of low-cost lifestyle interventions.

Lifestyle Medicine Challenges

As the national health care system evolves, lifestyle medicine will continue to play an increasingly important role. For lifestyle medicine to be fully implemented in primary care practices at the evidence-based levels currently recommended by national guidelines, several important steps must be taken. First, physicians must be convinced that they are adequately reimbursed for the lifestyle interventions they institute for

Table 4: Outpatient Billing for Lifestyle Medicine

Type of Visit	New Patient Time Requirements*	Established Patient Time Requirements*
Straightforward (99201 & 99211)	10 minutes	5 minutes (physician presence not required)
Straightforward (99202 & 99212)	20 minutes	10 minutes
Low Complex (99203 & 99213)	30 minutes	15 minutes
Moderate Complex (99204 & 99214)	45 minutes	25 minutes
High Complex (99205 & 99215)	60 minutes	40 minutes
* Time codes require: documentation of the total time spent face-to-face; a statement that "more than half" of the time was spent counseling and/or coordinating care; a summary of the visit content		

their patients. No matter how strong the idealism and education of the provider, eventually reimbursement drives physician behavior.

Second, health care providers must be educated to feel competent and efficacious in facilitating health behavior change. Physicians must know the science behind lifestyle interventions and the steps that lead to improved health choices that are sustained. They must be confident in their ability to listen to and assess the patient and to successfully motivate them toward healthier behaviors. Providers must have teams and community resources that will support their lifestyle prescriptions for better nutrition, physical activity, rest, and the other core lifestyle interventions. Both office-based and interactive technologies must continue to evolve as part of the support systems for both providers and patients outside of the typical office visit.

Third, the research base behind the application of lifestyle medicine must be strengthened. The science is strong regarding what constitutes a healthy lifestyle. It is apparent that health behaviors can change; lifestyle prescriptions do have value. What is not clear are the methods that need to be applied in the typical primary care office. Brief individual counseling works, but there is scant literature on lifestyle prescriptions, especially in the area of nutrition. The role of group visits appears promising, but again this format is not well studied for initiating and sustaining healthier lifestyles. Intensive therapeutic lifestyle change has been shown to be effective in a variety of institutional and community-based settings,[81,82] but when and how it is best applied to typical patient care is still to be defined.

Fourth, the roles of the lifestyle medicine team need to be clarified. Lifestyle interventions are likely best accomplished by physicians working with nutritionists, exercise physiologists, behavioral therapists, and a variety of other health care professionals. The ideal roles and ratios of various providers have not been discussed in the literature. The place of a lifestyle medicine specialist is also unclear. While the majority of lifestyle interventions will take place facilitated by primary care physicians in a medical home-type setting, it is likely that there is a place for specialists with more extensive training in health behavior change and lifestyle interventions who can facilitate intensive therapeutic lifestyle change for very high-risk patients in a variety of settings.

Finally, the public consciousness and desire for healthier lifestyles must outweigh the natural societal tendency to migrate to that which in the short term is easier and more enjoyable but in the long term leads to higher morbidity, mortality, and health care costs. It will really only be when we as a people demand healthier systems around food, physical activity, and medical care that the political, financial, and scientific communities will work together to fully implement a culture of wellness and healthy lifestyles.

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Physician CME Questions

27. Lifestyle medicine includes helping individuals and families adopt and sustain healthy behaviors that affect health and quality of life. It also includes which one of the following?
    A. therapeutic touch
    B. smoking cessation
    C. chemoprophylaxis
    D. appropriate supplement use

28. A health care provider competent in lifestyle medicine must be able to do which one of the following?
    A. implement an immunization tracking system
    B. perform a rapid cycle quality improvement initiative
    C. offer protein-sparing meal replacement options for weight loss
    D. prescribe focused food-based nutrition interventions

29. Successful health behavior change begins with a health habit assessment but should also include which one of the following?
    A. creation of a discrepancy between the patient's life goals and their current status
    B. a family of origin genetic analysis
    C. a patient entered electronic medical record based past medical history
    D. referral to a therapist who can implement cognitive behavioral change and group therapy

30. The primary focus of a nutritional lifestyle intervention should be which one of the following?
    A. decreased fat intake to less than 20% of total caloric intake
    B. inclusion of multi-grain bread and cereal products
    C. development of a whole food based diet
    D. customized nutraceutical prescriptions

31. An appropriate lifestyle intervention could all of the following *except*:
    A. exercise at the maximum heart rate 30 minutes/day, five days/week
    B. sleep 7.5 hours each night
    C. meditate 20 minutes/day, five days/week
    D. decrease alcohol use to one drink/day or less

CME Answer Key

27. B; 28. D; 29. A; 30. C; 31. A

Primary Care Reports

CME Objectives

Upon completion of this activity, participants should be able to:

- summarize recent, significant studies related to the practice of primary care medicine;
- evaluate the credibility of published data and recommendations related to primary care medicine;
- discuss the advantages and disadvantages of new diagnostic and therapeutic procedures in the primary care setting.

CME Instructions

Physicians participate in this continuing medical education program by reading the article, using the provided references for further research, and studying the questions at the end of the article. Participants should select what they believe to be the correct answers, then refer to the list of correct answers to evaluate their knowledge. To clarify confusion surrounding any questions answered incorrectly, please consult the source material. *After completing this activity, you must complete the evaluation form that will be provided at the end of the semester and return it in the reply envelope provided to receive a certificate of completion.* When your evaluation is received, a certificate will be mailed to you.

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Health Care Reform Update

What Health Care Reform Means to You A supplement to *Primary Care Reports*

Increased provider access tops list of what clinicians will like about HC bill

Changes will take a few years

HEALTH CARE CLINICIANS AND ORGANIZATIONS LIKELY will find that the new health care reform bill's positive features outweigh its drawbacks, experts say.

The Patient Protection and Affordable Health Care Act, signed into law on March 23, 2010, by President Barack Obama, provides a series of changes to take place to health care insurance coverage, Medicare, Medicaid, prescription drugs, quality improvement initiatives, medical malpractice, and other items. These are to be implemented from 2010 to 2014.

"The thing that is so big is the coverage for tens of millions of people who don't have health insurance now," says **Cecil Wilson**, MD, an internist in Winter Park, FL, and the president-elect of the American Medical Association in Chicago, IL.

People no longer will have to worry about losing health care coverage for existing diseases if they lose their jobs, and increasing numbers of people will have access to preventive care, primary care, and disease management, Wilson adds.

"Those are the big things that make this such a sea change in my opinion," he says. "For physicians, this is good because they won't have to worry about their patients' insurance being cut off, and thus putting their patients at risk."

Hospitals will find that significantly more patients will have health care coverage, resulting in a decline in uncompensated care, says **Caroline Steinberg**, vice president for trends analysis for the American Hospital Association of Washington, DC.

"We also would expect that demand for care from formerly uninsured patients will increase," Steinberg says. "Hopefully, we'll see some increases in primary care so by the time they hit the hospital they won't have some of the same kinds of problems they've had before."

The new bill provides billions of dollars in funding for clinics that provide primary care to uninsured, indigent, and immigrant patients. In 2014, it also expands Medicaid to all non-Medicare eligible individuals who have incomes up to 133% of the federal poverty level. These initiatives could help send more people to primary care services and keep them from using the emergency room for non-emergency care, Steinberg adds.

"We may [identify] more people with conditions that require specialty care because once people have access to coverage they tend to use more health care across all levels of the system," Steinberg says. "So that could go either way."

Plus, hospitals should expect the next few years to continue to be rough fiscally since most of the more significant provisions in the bill will not be fully implemented until 2014.

"Our hospitals are telling us that uncompensated care is going up because of job losses and loss of insurance, and these people show up in hospitals," Steinberg says.

There won't be much improvement in the immediate future until the economy recovers and the government provides more funding for Medicaid, she notes.

More oncology patients will have access to care, as a result of the bill's prohibition of lifetime limits on the dollar value of coverage, which begins Jan. 1, 2014. There is a temporary national high-risk pool to provide health care coverage to people with pre-existing medical conditions, which will be in place between June, 2010, and 2014.

"Many cancer patients who need repeated courses of treatment can easily exceed their caps and find themselves unable to afford needed treatment and medication," says **Allen S. Lichter**, MD, chief executive officer of the American Society of Clinical Oncology (ASCO), in a statement issued after the bill was signed.

By this fall, insurers will not be able to exclude children with pre-existing conditions from being covered by their family policy, and this also is a positive move, Lichter says.

The bill's focus on prevention and wellness will benefit infectious disease and public health initiatives.

"There are a few things in the bill that we're pleased to see stay in the final version," says **Michael Ochs**, government relations associate with the Infectious Diseases Society of America (IDSA) in Arlington, VA.

The bill's emphasis on wellness and disease prevention with billions of additional federal dollars for these is one example, Ochs says.

The bill's impact on physician and other provider payments is a more mixed bag, however. *(See story on*

physician payments, below.)

"There's a 10% incentive pay for primary care and general surgery," says **Jason A. Scull**, program officer for clinical affairs at IDSA.

"They're focusing on primary care in a lot of these new innovative payment models, but I think primary care does need to be incentivized," Scull says.

But the drawback is that cognitive specialists, like infectious disease specialists, cardiologists, and neurologists, could be shortchanged as the pie is cut differently, but not expanded.

"There will be unintended consequences," Scull notes. "Already last year the Centers for Medicare & Medicaid Services [CMS] eliminated payments for consultation codes that cognitive specialties use to give them money to distribute elsewhere in the fee schedule and to send more to primary care physicians."

This redistribution of payments might result in fewer medical students choosing to spend extra years of training beyond their general internal medicine residency, he adds.

While the sweeping health care reform provides some specifics on how changes will occur in the industry, no one knows precisely how things will change until the regulatory details emerge, the experts say.

"There are a lot of moving pieces to this," Scull says. "I think it's anybody's guess to where all of this ends up." ■

Doctors will be more closely scrutinized with bill's provisions

Experts talk about bill's negatives

PAY ATTENTION TO THE NEW HEALTH CARE BILL'S REGulatory details, experts warn providers.

There are some items in the sweeping legislation that could result in more documentation, work, and risk for physicians and other providers.

For instance, the new bill makes it clear that the government wants doctors to be doctors and not own hospitals, says **LaDale K. George**, JD, a partner with Neal, Gerber, Eisenberg in Chicago, IL.

The bill puts a moratorium on any physician-owned hospitals in non-rural settings that were not Medicare providers as of December 2010.

"The new law says that the practice of physicians owning hospitals no longer is allowed," he explains. "If a physician owns or has a financial interest in a hospital and refers patients to that hospital then every service the patient receives at the hospital is a Stark violation of $25,000 per incident."

Also, the anti-kickback law has been changed by the new bill.

"The way the new act changes it is that it appears to eliminate the need to have actual knowledge or specific intent to violate the statute," George says. "It moves in the direction of where the Stark law is where if you do not meet the safe harbors in which providers can refer to one another and engage in commercial practices together then you will be viewed as being guilty."

From physicians' perspectives, some of the other requirements will be more onerous, particularly as far as documentation and accounting are concerned.

For instance, the bill's Physician Payment Sunshine Provision requires physicians to disclose every payment they receive from pharmaceutical and biotech companies in excess of $100, and this includes drug samples. This could prove to be an accounting problem for physician investigators and others.

This likely will be a headache to physicians, who will have to keep track of every sample they receive and every payment that flows through to them for research, George says.

The new health care bill also appears to give physicians incentives and/or penalties depending on their compliance with reporting data as part of the physician quality reporting initiative (PQRI), which was established with the 2006 Tax Relief and Health Care Act.

"What's clear is that Congress is moving into the direction of mandating physicians to participate in PQRI and also moving in the direction of mandating physician resource use reporting," says **Jason A. Scull**, program officer for clinical affairs at the Infectious Diseases Society of America.

"These are somehow merged into a value modifier that also will adjust payment based on the quality of care they provide," Scull says.

About one of six eligible physicians now makes the reports, and about half of these receive incentive payments, he adds. ■

Primary Care Reports

Reader Survey 2010

In an effort to ensure *Primary Care Reports* is addressing the issues most important to you, we ask that you take a few minutes to complete and return this survey.
Instructions: Mark your answers by filling in the appropriate bubbles. Please write in your answers to the open-ended questions in the space provided. Return the questionnaire in the enclosed postage-paid envelope. The deadline is **July 15, 2010.**

In future issues of *Primary Care Reports*, would you like to see more or less coverage of the following topics?

A. more coverage	B. less coverage	C. about the same amount
1. Cardiology	○ A	○ B	○ C
2. Infectious disease	○ A	○ B	○ C
3. Neurology	○ A	○ B	○ C
4. Endocrinology	○ A	○ B	○ C
5. Psychiatry	○ A	○ B	○ C
6. Gastroenterology	○ A	○ B	○ C
7. Rheumatology	○ A	○ B	○ C
8. Allergy and immunology	○ A	○ B	○ C
9. Oncology	○ A	○ B	○ C
10. Pulmonology	○ A	○ B	○ C

11. What other topics would you like to see discussed in *PCR*?

_____

_____

12. What type of information not currently provided in *Primary Care Reports* would you like to see added?

_____

_____

18. Are the articles in *PCR* written about issues of importance and concern to you?

A. always ○
B. most of the time ○
C. some of the time ○
D. rarely ○
E. never ○

19. Please describe your work place.

A. private practice ○
B. hospital ○
C. government institution ○
D. research ○
E. other_____

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Clinical Briefs in
Primary Care™

The essential monthly primary care update

By Louis Kuritzky, MD

Supplement to *Clinical Cardiology Alert, Clinical Oncology Alert, Critical Care Alert, Hospital Medicine Alert, Infectious Disease Alert, Neurology Alert, OB/GYN Clinical Alert, Primary Care Reports.*

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Statins and risk of developing diabetes

Source: Sattar N, et al. Statins and risk of incident diabetes. *Lancet* 2010;375: 735-742.

There is little dispute regarding the beneficial reduction in CV events seen with statin treatment of dyslipidemic patients. At the same time, however, conflicting evidence has suggested that statin treatment might be associated with an increased risk of new-onset diabetes.

Sattar et al performed a meta-analysis of data from large statin clinical trials (n = 13), totalling almost 100,000 patients. During a mean follow-up of 4 years, 9% more individuals developed new diabetes on a statin than patients not treated with a statin. Since CV risk reduction was still favorably influenced by statin treatment, this small increase incidence of diabetes was either not sufficient to offset other beneficial vascular effects, or, once diabetes developed, statin protection was already on board, or perhaps both factors were influential.

You may recall that in hypertension treatment trials, a similar problem has been identified. Chlorthalidone (ALLHAT) had a significantly greater risk for incidence of new diabetes than comparators, yet this adverse effect did not seem to adversely affect CV event rates.

The mechanism by which statins increase risk for diabetes is obscure. This data analysis calculated that 255 subjects would have to be treated with a statin for 4 years to incur 1 additional new case of diabetes. Fortunately, if the small increase is real, it is strongly counterbalanced by well-documented reductions in CV events.

Maximize benefits of metform in DM2

Source: Brown JB, et al. Secondary failure of metformin monotherapy in clinical practice. *Diabetes Care* 2010;33:501-506.

To date, controlled trials indicate that no matter what pharmacotherapy is used to control glucose in type 2 diabetes (DM2), one can anticpate a progressive loss of control over time. Loss of efficacy is termed secondary failure: An initially effective medication later becomes insufficient to maintain control. It seems to me that this is too harsh an indictment of pharmacotherapy, since even if the medication continues with similar action over long time periods, confounders such as weight gain, inherent disease progression, and addition of confounding comorbidities might make it appear as if the medication is failing, when in reality, counterbalancing forces are increasing.

In any case, Brown et al performed an observational cohort study of DM2 subjects (n = 1799) initially treated with metformin monotherapy successfully (i.e., able to maintain an A1c < 7.0 without adding a second agent). Secondary failure was defined as either the addition of a second agent, or an increase of A1c above 7.0 while still on monotherapy. Subjects who required additional therapy within the first 6 months of metformin treatment were regarded as primary failure, and were excluded from this analysis.

In subjects able to maintain good control with initial metformin monotherapy, secondary failure occurred at a rate of 17% per year. Predictors of higher failure rates included longer duration of diabetes before treatment and higher baseline A1c at initiation of treatment. These data suggest that early initiation of treatment, especially when A1c is not yet markedly elevated, results in greater durability of metformin efficacy.

Prediabetes therapy and beta-cell function

Source: Hanley AJ, et al. Effect of rosiglitazone and ramipril on {beta}-cell function in people with impaired glucose tolerance or impaired fasting glucose. *Diabetes Care* 2010;33:608-613.

Prediabetes (pDM) is defined as either impaired fasting glucose (FBG = 100-125 mg/dL), impaired glucose tolerance (IGT; 2-hour post-load glucose = 140-199 mg/dL), or supranormal but not diabetic A1c (A1c = 5.7-6.4). Untreated pDM predictably progresses to frank DM at a rate of about 7%-10% per year. Numerous interventions have been shown to alter the progression from pDM to diabetes, including diet, exercise, metformin, acarbose, orlistat, and thiazolidinediones; this year, nateglinide, an insulin secretagogue, was not confirmed to delay progression from pDM to diabetes.

Hopefully, treatments to prevent diabetes will also impact beta-cell function favorably, rather than simply compensate for progressive metabolic decline. The DREAM trial (Diabetes Reduction Assessment with Ramipril and Rosiglitazone Medication) randomized 5269 pDM subjects to ramipril and/or rosigliatoze. A substudy of DREAM (n = 982) had measurements of beta-cell function at baseline and periodically during the 3-year (median) follow-up, as well as measurements of progression from pDM to DM.

Subjects randomized to ramipril did not experience any meaningful change

in beta-cell function. In contrast, rosiglitazone-treated subjects enjoyed substantial improvements in beta-cell function. Benefits were less in pDM subjects who only manifest IFG compared with IGT or both.

In addition to reducing beta cells induced by glucotoxicity, thiazolidinediones lower free fatty acid levels, which may favorably affect beta-cell apoptosis.

Onychomycosis: Long-term follow-up

Source: Piraccini BM, et al. Long-term follow-up of toenail onychomycosis caused by dermatophytes after successful treatment with systemic antifungal agents. *J Am Acad Dermatol* 2010;62:411-414.

Although onychomycosis (ONCM) is often considered a cosmetic problem, some patients suffer significant disability due to foot pain, and difficulty wearing shoes. The treatment course for toenail ONCM is lengthy and costly. There are few data on long-term follow-up to ascertain recurrence rates, although prevailing opinion suggests recurrence is common.

Praccini et al performed a prospective study of ONCM patients (n = 73) who had been treated with pulse therapy (treatment 1 week/month for 6 months) with terbinafine or itraconazole. After clinical cure, subjects were prospectively followed for 7 years. Cure was defined as normalized clinical appearance and negative fungus culture.

Patients were seen every 6 months during follow-up. Overall, recurrence developed in 16.4% of subjects. Each case of recurrence involved the same organism identified in the original infection. However, the recurrence rate for itraconazole was 3-fold greater than terbinafine. Terbinafine is widely regarded as the treatment of choice for toenail ONCM; this trial suggests superior durability of cure for terbinafine when compared with itraconazole.

Diagnostic yield of elective coronary angiography

Source: Patel MR, et al. Low diagnostic yield of elective coronary angiography. *N Engl J Med* 2010;362:886-895.

Current recommendations suggest that in stable persons under consideration for CAD evaluation, low-risk individuals be observed, high-risk patients be triaged to coronary angiography, and intermediate-risk persons be further stratified by means of non-invasive testing. Such guidance is structured to minimize unnecessary invasive investigations in low-risk individuals, and to identify — in the group of intermediate risk — those who merit follow-up with angiography.

The American College of Cardiology National Cardiovascular Data Registry provided information on patients without known CAD (n = 398,978) who received coronary angiography (electively) at hospitals in the United States during a 4-year interval commencing January, 2004.

Obstructive CAD was defined as at least 50% stenosis of the left main coronary artery (or greater degrees of stenosis of epicardial vessels). Catheterization determined that slightly more than one-third of patients had obstructive CAD. In addition to the disappointingly low percentage of individuals identified with CAD on angiography, this study also provided insights about the concordance of risk and use of non-invasive testing (i.e., stress testing). When non-invasive testing had preceded angiography, subjects' baseline risk category was at odds with the current recommendations focusing upon refinement of risk in persons at intermediate Framingham scores, in that those with high Framingham risk scores were disproportionately represented. The authors suggest that the diagnostic yield based upon current practice needs improvement.

Thyroid hormone analogue for dyslipidemia

Source: Ladenson PW, et al. Use of the thyroid hormone analogue eprotirome in statin-treated dyslipidemia. *N Engl J Med* 2010;362:906-916.

The role of statins in treatment of dyslipidemia is well established. There are, however, limitations of statins: Residual risk is substantial, not all persons can tolerate statins, and, even with full-dose statin treatment, some patients do not achieve lipid goals.

The role of the thyroid in lipid metabolism has long been a matter of scientific interest. It is recommended that patients with dyslipidemia undergo thyroid function testing since hypothyroidism, although only present in a small percentage of dyslipidemic patients, is readily correctible and offers meaningful lipid improvements. Enhancement of thyroid activity has favorable lipid effects. As far back as the 1960s, investigators were curious enough about thyroid hormone and vascular disease to enroll men in the Coronary Drug Project (1965) and randomize them to d-thyroxine, which was felt at the time (mistakenly) to have essentially no effect on sympathetic nervous system sensitivity, but favorable effects on lipids.

Eprotirome (EPR) is an analogue of thyroid homone which has preferential affinity for thyroid receptors that modulate lipid lowering, as compared to cardiac receptors. A randomized placebo-controlled, double-blind study was done among patients on an NCEP step 1 diet and a statin (simvastatin or atorvastatin). Patients (n = 329) received statin plus either EPR or placebo for 12 weeks.

At the end of the trial, very favorable lipid effects were reported with the addition of EPR to a statin: a 22%-32% reduction in LDL, a 6- to 9-fold increase in patients achieving an LDL < 100 mg/dL, as well as favorable effects on triglycerides and apoB (all dose-dependent). A small reduction in HDL was seen. There was no change in heart rate or BP. Selective activation of thyroid receptors may one day provide an additional path for successful lipid modulation.

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Finding ACCORD in the Management of Type 2 Diabetes?

In this issue: Examining the three arms of the ACCORD trial; and FDA Actions: clopidogrel, dexlansoprazole, and tamsulosin.

ACCORD and type 2 diabetes

Every once in a while a medical study comes along that turns medical dogma on its ear. The Multiple Risk Factor Intervention Trial (MRFIT), published in 1982, was such a study, so was the Women's Health Initiative (WHI), published in 2002. Both studies challenged conventional wisdom and changed practice. MRFIT caused us to take a hard look at risk factor intervention especially hypertensive treatment, while WHI established that combination hormone therapy in postmenopausal women should no longer be routinely recommended because of the risk of breast cancer and heart disease.

The Action to Control Cardiovascular Risk in Diabetics (ACCORD) trial, published in March in the *New England Journal of Medicine*, is also such a study, and is destined to change medical practice in the treatment of type 2 diabetes. ACCORD looked at three aspects of care in type 2 diabetes, the first was the effects of intensive glucose lowering, the second was the effect of intensive blood pressure control, and the third was the effect of combination lipid therapy.

The intensive glucose lowering study was published early in 2008 when it was found that the intensive therapy group (targeting hemoglobin A1c < 6.0%) reported a higher mortality than the standard therapy group (targeting A1c 7.0%-7.9%). At the same time, intensive therapy did not significantly reduce major cardiovascular events (*N Engl J Med* 2008;358:2545-2559).

The second and third wings of the ACCORD trial were published on-line March 14, and the results were similarly discouraging for aggressive care. A total of 4733 participants with type 2 diabetes were enrolled in the intensive blood pressure control wing and were randomized to intensive therapy, targeting a systolic pressure < 120 mmHg, or standard therapy targeting a systolic blood pressure < 140 mmHg. The primary composite outcome was nonfatal myocardial infarction, nonfatal stroke, or death from cardiovascular causes. After a mean follow-up of 4.7 years, mean target blood pressures were met in both groups. The annual rate of the primary outcome was 1.87% in the intensive therapy group and 2.09% in the standard therapy group (hazard ratio [HR], 0.88; 95% confidence interval [CI], 0.73-1.06; $P = 0.20$). The annual rates of death from any cause were 1.28% in the intensive therapy group and 1.19% in the standard therapy group (HR, 1.07; 95% CI, 0.85-1.35; $P = 0.55$). There was a slightly reduced risk of stroke in the intensive therapy group (0.32% vs 0.53%; $P = 0.01$); however, serious adverse events were more than double in the intensive therapy group. The authors conclude

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that in patients with type 2 diabetes targeting systolic blood pressure < 120 mm Hg as compared to < 140 mm Hg did not reduce the rate of the composite outcome of fatal and nonfatal major cardiovascular events (*N Engl J Med* published on-line March 14, 2010). While these results are somewhat surprising, they may not change the general recommendation for more aggressive blood pressure management in type 2 diabetes to systolic blood pressure ≤ 130/80 mm Hg, which is consistent with most current guidelines (including JNC VII).

In the third wing of ACCORD, 5518 patients with type 2 diabetes who were being treated with the statin simvastatin were randomized also to receive fenofibrate or placebo. The primary outcome was first occurrence of nonfatal myocardial infarction, nonfatal stroke, or death from cardiovascular causes. After a mean follow-up of 4.7 years, the annual rate of primary outcome was 2.2% in the fenofibrate group and 2.4% in the placebo group (HR 0.92; 95% CI, 0.79-1.08; P = 0.32). There were also no significant differences between the two study groups with respect to any secondary outcomes or death rate. Subgroup analysis suggested slightly higher benefit for men vs women and perhaps a benefit for those with high baseline triglycerides (> 204 mg/dL) and low HDL (≤ 34 mg/dL). The authors conclude that the combination of fenofibrate and simvastatin did not reduce the rate of fatal cardiovascular events, nonfatal myocardial infarction, or nonfatal stroke compared with simvastatin alone (*N Engl J Med* published on-line March 14, 2010). This study does not in any way diminish the known benefit from aggressive statin therapy in type 2 diabetics, but does suggest that targeted treatment of triglycerides with fenofibrate is of no value. The FDA is reviewing the ACCORD data, but as of this time they have "made no new conclusions or recommendations regarding the use of simvastatin or other statin drugs and fenofibrate."

Do statins increase the risk of type 2 diabetes? It has been suggested that lipophilic statins may cause unfavorable metabolic side effects such as reduction of insulin secretion and worsening of insulin resistance. In a small single-blind, placebo-controlled parallel study, 40 to 44 patients were randomized to receive placebo, or atorvastatin 10, 20, 40, and 80 mg during a 2-month period. While atorvastatin significantly reduced LDL and apolipoprotein B levels, the drug was also associated with significantly increased fasting plasma insulin levels, as well as hemoglobin A1c levels (mean changes in fasting insulin levels, 25%, 42%, 31%, and 45%, respectively, for increasing dose; A1c increases of 2%, 5%, 5%, and 5%, respectively; $P < 0.05$ by paired t-test). Atorvastatin also decreased insulin sensitivity in a dose-responsive fashion. The authors conclude that atorvastatin resulted in significant increases in fasting insulin, hemoglobin A1c consistent with increased insulin resistance (*J Am Coll Cardiol* 2010;55:1209-1216). Previous studies have shown similar results with lipophilic statins including atorvastatin, rosuvastatin, and simvastatin, while pravastatin seems to reduce the risk of diabetes.

FDA Actions

The FDA has issued a warning to health care providers regarding the antiplatelet drug clopidogrel (Plavix®). It is recently been found that up to 14% of the population did not metabolize the drug effectively and may not fully convert the drug to its active form. Clopidogrel is dependent on CYP2C19 and those that genetically lack the enzyme may not convert the drug to its active form. Recent studies have suggested that reduced CYP2C19 activity was associated with higher risk for cardiovascular outcomes. A test is available to identify genetic differences in CYP2C19 function and the FDA is recommending that health care professionals consider use of other antiplatelet medications or use alternative dosing if patients are poor metabolizers. The manufacturer of Plavix is being asked to add a black box warning to the drug labeling to this effect. Previously, it was discovered that some proton pump inhibitors including omeprazole may also inhibit metabolism to the active drug. Meanwhile Eli Lilly's prasugrel (Effient®), a direct competitor to clopidogrel, is not affected by CYP genetic variants.

The FDA has approved Takeda Pharmaceutical's request to change the name of its proton pump inhibitor dexlansoprazole from Kapidex® to Dexilant™. The change is being made due to several dispensing errors that occurred between Kapidex and the prostate cancer drug Casodex® (bicalutamide) and the analgesic Kadian® (morphine).

The FDA has approved a generic version of Boeringer Ingelheim's tamsulosin (Flomax®) for the treatment of benign prostatic hyperplasia in men. Generic tamsulosin should be available later in 2010.