A new paradigm of cardiovascular risk factor modification

Muhammad Firdaus[1]
Jeffery M Asbury[2]
Dwight W Reynolds[2]

[1]Donald W Reynolds Department of Geriatric Medicine, University of Oklahoma, Oklahoma City, OK, USA; [2]Department of Medicine, Cardiovascular Section, University of Oklahoma, Oklahoma City, OK, USA

Abstract: Atherosclerotic cardiovascular diseases (CVDs) are the leading cause of death and disability in the United States. While multiple studies have demonstrated that modification of atherosclerotic cardiovascular risk factors (CVRFs) significantly reduces morbidity and mortality rates, clinical control of CVDs and CVRFs remains poor. By 2010, the American Heart Association seeks to reduce coronary heart disease, stroke, and risk by 25%. To meet this goal, clinical practitioners must establish new treatment paradigms for CVDs and CVRFs. This paper discusses one such treatment model – a comprehensive atherosclerosis program run by physician extenders (under physician supervision), which incorporates evidence-based CVD and CVRF interventions to achieve treatment goals.

Keywords: atherosclerosis, cardiovascular risk factors, prevention, modification

Atherosclerosis: the failure to achieve treatment goals

Atherosclerotic cardiovascular diseases (CVDs) have, for decades, been the leading cause of death and disability in men and women in the United States (AHA 2005a). There is convincing evidence that treating atherosclerotic cardiovascular risk factors (CVRFs) (eg, elevated levels of low-density lipoprotein cholesterol [LDL-C], high blood pressure [BP], and smoking) reduces cardiovascular morbidity and mortality. This is consistent across a broad range of patients, including those with particular medical conditions (coronary artery disease [CAD], diabetes, and hypertension) and those from particular demographic groups (smokers, non-smokers, women, and the elderly) (Galen 1988; Rosenburg 1990; 4S Study Group 1994; Shepherd 1995; Voors 1996; Downs 1998; van Erkel 1999; Neal 2000; Collins 2002; Sever 2003). As a result of these findings, professional societies and organizations have established standards of practice and treatment goals that are tailored to address CVDs and CVRFs in different populations. For example, the American Diabetes Association has established the following recommendations for treating patients with diabetes, which is now considered a CAD-risk equivalent (Table 1) (Haffner et al 1998; NCEP ATP III 2001; ADA 2003; Gibbons et al 2003).

While meeting these treatment goals has proven effective in combating CAD, a review of the current literature reveals that in clinical practice only a small percentage of patients actually *achieve* the recommended treatment goals. Indeed, just 18%–25% of adult patients with CAD and/or heart failure met the National Cholesterol Education Program (NCEP) goal for LDL-C (Sueta et al 1999; Pearson et al 2000). Similarly, among hypertensives, BP was adequately controlled in just 31% of patients, and among diabetics, BP was controlled in just 25% (Hajjar

Correspondence: Muhammad Firdaus
PO Box 26901, WP 1215, Oklahoma City, OK 73190, USA
Tel +1 405 271 3450
Fax +1 405 271 2497
Email muhammad-firdaus@ouhsc.edu

Table 1 Recommended treatment goals for patients with type 2 diabetes mellitus

	Clinical indicator of the vascular risk factor	Recommended goal
1	Hemoglobin A1C	< 7%[a]
2	Low-density lipoprotein cholesterol	< 100 mg/dL (< 2.6 mmol/L)
3	High-density lipoprotein (HDL-C) cholesterol	40 mg/dL (men) (> 1.1 mmol/L)[b]
4	Triglycerides	< 150 mg/dL (< 1.7 mmol/L)
5	Blood pressure	< 130/80 mmHg
6	Aspirin therapy (75–325 mg/day)	Adults with diabetes and macrovascular disease
7	Statins	Patients with type 2 diabetes and other cardiovascular risk factors (Snow 2004)
8	Microalbuminurea	< 30 µg/mg of creatinine
9	Therapeutic lifestyle modifications	Increased physical activity and healthy diet
10	Tobacco smoking	Counsel about cessation and offer therapy

Source: Data adapted from ADA (2003).
[a] Referenced to a nondiabetic range of 4.0%–6.0% using a Diabetes Control and Complications Trial-based assay.
[b] For women, it has been suggested that the HDL goal be increased by 10 mg/dL.

and Kochen 2003). A mere 2% of current smokers quit permanently each year (CDC 2000).

While multiple factors are responsible for the failure to achieve treatment goals for CVRFs, patient nonadherence to drug therapy is arguably the most primary. Among the common causes of nonadherence are: patient misunderstanding of the condition or treatment; denial of illness due to lack of symptoms; perception of medication as a symbol of ill health; lack of patient involvement in the care plan; and unexpected adverse side effects (Chobanian et al 2003). Additional barriers to successful drug adherence include those related to the complexity of care; ie, cost of medication and lack of financial resources, limited transportation, difficulty scheduling appointments amid life's competing demands, and patient difficulty with polypharmacy or failure to uptitrate (Phillips et al 2001; Chobanian et al 2003; Foley et al 2003). Sometimes the likelihood for nonadherence can be identified by particular patient demographics, enabling doctors to be vigilant with patients at high risk. For example, male hypertensive patients aged 65 or older who had not visited a physician within the preceding 12 months were most likely to have poor control of hypertension (Hyman and Pavlik 2001).

How can achievement of treatment goals be improved?

Improving medication adherence

Behavioral models suggest that the most effective therapy prescribed by the most careful physician will achieve treatment goals only if the patient is motivated to take the prescribed medication and to establish and maintain a healthy lifestyle (Chobanian et al 2003). Patient motivation can be encouraged in a number of ways. First, each patient's cultural background, belief system, and previous experiences with the healthcare system uniquely influence his or her attitude toward the use of medication and must be taken into consideration by the physician (Betancourt et al 1999). Tailoring his or her interaction to these considerations, the physician should demonstrate empathy and build trust with the patient, creating a positive patient–physician experience that results in increased patient motivation (Barrier et al 2003). To specifically promote drug adherence, physicians should encourage patients to share any concerns or fears of unexpected or disturbing drug reactions, and then help to mitigate those fears by expressing empathy and informing the patient of what to do if those reactions occur (Chobanian et al 2003).

Motivation also improves if the patient and physician agree upon achievable treatment goals and specific strategies and timelines for meeting those goals (NCEP ATP III 2001). When a patient does not meet a goal, the treatment plan should be modified according to mutually agreed upon changes (Balas et al 2000; Boulware et al 2001). Finally, decision support systems, flow sheets, templates, feedback reminders, involvement of nurse practitioners, and clinical pharmacists have also proved to be helpful (Balas et al 2000).

Other strategies for achieving treatment goals

Fonarow et al (2001) have demonstrated that in patients with established CAD, initiating a program of aspirin, statin, beta-blocker, and angiotensin-converting enzyme therapy in conjunction with lifestyle counseling, before hospital discharge, increased post-discharge use of statins from 10% to 91%. This adherence translates into a significant increase in the number of patients achieving the LDL-C goal of ≤ 100 mg/dL (from 6% to 58%), and a significant decrease in the rate of death and nonfatal myocardial infarction (from 14.8% to 7.3%).

Other successful strategies for improving the achievement of treatment goals include: nurse specialist-

led hypertension and dyslipidemia clinics (Allen et al 2002; New et al 2003); combination of two of more medications (Black et al 2001; Cushman et al 2002); BP self-measurement (which is helpful in evaluating "white-coat" hypertension, diagnosing hypertension, and preventing potential problems) (AHA 2005b); and smoking cessation interventions (behavioral and pharmacological) (Burt et al 1974; Pozen et al 1977; Taylor et al 1990; DeBusk et al 1994; Carlsson et al 1997; Dornelas et al 2000; Hopkins et al 2001; Zhu et al 2002; Hilleman et al 2004) geared toward CAD patients, which involve a high number of contacts and are of prolonged duration.

A new paradigm for the treatment of CVRFs and CVDs

To address America's failure to clinically replicate the successes of multiple randomized studies – to bring the successes of these studies from the research bench to the bedside – the American Heart Association has established the ambitious goal to reduce coronary heart disease, stroke, and risk by 25% over current levels by 2010 (Smaha 2000). If we are to meet this goal, the focus of treatment of CVDs must change from treating the symptoms of target organs (such as CAD, stroke, peripheral arterial disease) to the comprehensive treatment of the underlying disease process of *atherosclerosis*.

Since atherosclerosis is caused by multiple modifiable (ie, preventable) risk factors, it follows that practitioners in primary care clinics – those on the "front lines" of preventive care – should be the leaders in this new approach. There is an urgent need to design, test, and implement evidence-based programs in outpatient primary care settings devoted to the primary and secondary prevention of atherosclerosis. The authors have recently launched such a program – The Prevention of Heart Attack and Stroke in the Elderly (PHASE) Clinic – and are currently conducting a 6-month long feasibility trial to measure its performance against usual care.

The design of the PHASE Clinic

Designed explicitly for the comprehensive modification of CVDs and CVRFs, the PHASE Clinic is a half-day weekly program embedded within a primary care practice of physicians. The clinic is run jointly by a physician extender (physician assistant or nurse practitioner) and a supervising physician. The clinic treats adult and elderly patients (ie, ≥ 50 years) with CVDs and CVRFs, such as established atherosclerosis of any artery, diabetes, obesity, the metabolic syndrome, dyslipidemia, hypertension, or smoking. Patients are initially seen by the physician, with subsequent visits scheduled with the physician extender. Patients are scheduled every 30 minutes.

PHASE interventions

1. *Lifestyle modification.* The clinic provides focused counseling regarding lifestyle modification, including weight loss, heart protective dietary choices, adoption of physical activity, and smoking cessation. We follow NCEP adult treatment panel III (NCEP ATP III 2001) recommendations, and utilize techniques from the "transtheoretical or stages of change" model for counseling (Greene et al 1999; Sarkin et al 2001; Anderson et al 2002) (see Appendix A).
2. *Patient's commitment and education materials.* At the end of lifestyle counseling, the patient and healthcare provider set achievable goals for each identified risk or disease, which are itemized on a form (Appendix A) that serves as both a motivational "contract" and an educational tool. Patients are asked to make a commitment to the program by initialing the counseling form, which is then initialed by the healthcare provider. Patients receive a copy of this double-sided form, which in addition to the patient's individualized goals, also includes educational information about weight loss, heart protective dietary choices, adoption of physical activity, and smoking cessation. Patients are advised to refer to it frequently, follow its instructions, and bring it to the next visit.
3. *Frequent uptitration and/or use of alternative pharmacotherapy.* The clinic employs pharmacotherapy for atherosclerotic coronary artery disease, carotid artery atherosclerosis, peripheral artery atherosclerosis, diabetes, obesity, the metabolic syndrome, dyslipidemia, hypertension, and smoking cessation. If condition-specific medications are tolerated by the patient, we frequently uptitrate; when a particular treatment is not tolerated, we employ alternative medications.
4. *Minimizing polypharmacy.* Polypharmacy is minimized by following Beers Criteria for potentially inappropriate medication use in older adults (Fick et al 2003).
5. *Improving medication adherence.* Clinic health providers utilize proven strategies to promote patient motivation and improve medication adherence, including demonstrating empathy, building trust, and cultivating

a positive experience during clinic visits (Barrier et al 2003). When considering specific treatment regimens, practitioners take into account patients' cultural and religious beliefs and previous experiences with the healthcare system (Betancourt et al 1999). Similarly, practitioners individually tailor each treatment regimen and timeline, taking into account each patient's readiness for change (Boulware et al 2001). Moreover, when a patient does not meet a CVRF's recommended goal, treatment plan changes are only implemented after active negotiations with the patient. Other strategies employed to facilitate treatment adherence include use of practice guidelines (from the American Heart Association/ American College of Cardiology, NCEP ATP III, and American Diabetic Association), flow sheets, templates, and confidential feedback postcard reminders about laboratory or imaging results (Balas et al 2000).

6. *Addressing socioeconomic challenges.* When patients face financial and other burdens that prevent their successful adherence to the program (eg, inability to purchase medications, difficulty in scheduling appointments, limited transportation), the clinic refers them to social services with support mechanisms that mitigate these needs.
7. *Monitoring home-based treatment.* Patients are asked to monitor their disease status at home by recording blood sugar, BP, pulse and weight; wearing a pedometer; keeping food and activity diaries; and bringing these records for review to each clinic visit. Patients with impairment in daily living activities and/or cognitive deficits are referred to home health or state-sponsored programs (that provide nursing home-level care at patients' residences) for monitoring and medication compliance.
8. *Referral to specialists.* As clinically indicated, practitioners refer patients to specialists such as dieticians, nutritionists, psychologists, diabetologists, and cardiologists.
9. *Close follow-up.* Patients are closely followed up in the clinic a minimum of once every three months and more frequently if necessary.

Outcome measures of the PHASE Clinic

The outcome measures of the PHASE Clinic include change in patient's body weight, BMI, waist circumference, BP, triglycerides, total cholesterol, LDL-C, HDL-C, hemoglobin A1C, urine microalbumin, and compliance rate with yearly diabetic retinal examination, diabetic foot examination at every visit, use of aspirin, beta-blockers, angiotensin-converting enzyme inhibitors, and statins, and diet, physical activity, and smoking cessation counseling, as indicated and individualized for patients. The PHASE Clinic (with 100 patients) is the unit of randomization, and its outcome measures will be compared with those of usual primary care clinic (with 100 patients) providing similar services to adult and elderly patients.

Financing for the PHASE Clinic

The medically necessary services provided in the PHASE Clinic are reimbursed through Medicare and other insurance.

Conclusion

Atherosclerosis is a potentially preventable multifactorial disease. Current literature reveals that most patients with established CVDs or CVRFs are failing to achieve their treatment goals. A dedicated, comprehensive atherosclerosis outpatient program run by a physician extender and supervising physician is a potentially successful model for improvement of treatment goals of CVRFs. As outcomes for the PHASE Clinic feasibility study become available, the authors will publish these findings so that other clinicians may replicate the model's anticipated successes.

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Appendix A

An example of a nutrition, physical activity, and smoking cessation counseling and patient education handout.

NuActive Lifestyle ©

Nutrition, Activity, and Smoking Cessation

Prevent Heart Attack, Stroke, and Early Death

1. OVERWEIGHT OR OBESITY

Are you overweight or obese?

Healthy weight = healthy Body Mass Index or BMI (body weight divided by square of height) = 18.5 to 24.9

Overweight means a BMI ≥ 25. Obesity means a BMI ≥ 30. Current BMI……. Current weight …….

Health Risks of Obesity or Overweight: Heart attack, stroke, high blood pressure, diabetes, osteoarthritis, lung problems, and premature death. These health risks can be reversed or improved by achieving a healthy weight.

Do you want to lose weight? Yes___ No___ (Recommended weight loss: 10% of body weight in 6 months. Lose ½ to 1 lb per week).

Lose 200 kilo calories (kcal) a day = about 10 pounds in 6 months = about 50 lb in 2 & ½ years.

If you eat 200 kcal less every day or burn 200 kcal more every day, you will lose 10 pounds in 6 months (182 days): 200 kcal × 182 days = 36,400 kcal deficit in 6 months. Since 3,500 kcal = 1 lb of body fat (Whitney and Rolfes 1996). Therefore, 36,400 kcal = **10.4 Lb of wt loss in 6 months = about 50 Lb in 2 & ½ years**

Cut 200 kcal from your day, for example about 20 French fries, 4 Oreo cookies, 16-ounce Coca-Cola, 40 peanuts.

How Much Should We Eat? Eat smaller portions (size of the palm of your hand for meat). Read the labels to find out portion size. Start low, go slow.

Adjusted total daily calorie need to induce weight loss, maintain desirable weight or prevent weight gain =_____

Goal:……

2. HEALTHY FOOD CHOICES

What food items did you eat within last 24 hours (McGee et al 1982)? Do you want to adopt healthy eating habits? Yes___ No___

……

	Focus on healthy foods	Examples

continued overleaf

1	High fiber (20-30 g/d) complex **carbohydrates** (50-60%)	Whole grains, legumes/beans, vegetables, nuts, & fruits
2	Replace saturated **fats** (total fat intake 25-35%) and cholesterol with mono- (up to 20% of total fat) & poly-unsaturated fats (up to 10% of total fat)	Fish, nuts, olive or canola oils; add plant stanols/ sterols 2 g/d (eg, Take Control or Benecol)
3	**Proteins** (15%)	Soy, beans, nuts, fish & chicken
4	Drink **water**	8 cups (about half a gallon) daily
5	**Eat less:** Cholesterol (<200 mg/d), saturated fats (<7% of total calories) **Avoid:** Trans fats, sweets, simple sugar, salt, & high calories.	

Goal:……

3. PHYSICAL ACTIVITY

How much weekly physical activity do you do? Do you want to increase your physical activity? Yes___ No___

……

Health Risks of Physical Inactivity: Heart attack, stroke, high blood pressure, diabetes, osteoporosis, gallstones, colon cancer, disability, and premature death. These health risks can be improved by regular physical activity.

Surgeon General's Recommendation: "30 minutes or more of moderate physical activity on all, or most, days of the week." Example: Brisk walking or gardening for 30 minutes (CDC 1996). Or physical activity to burn 200 kcal per day.

Walk, Walk, Walk – 10,000 Steps Daily: 10,000 steps = 5 miles = 500 kcal burned.

Get a Pedometer and count your steps. Try to do 10,000 steps every day. Start low, go slow.

Goal:……

4. CIGARETTE SMOKING CESSATION: Do you smoke? Yes___ No___ Do you want to quit? Yes___ No___

Health risks of smoking

Smoking increases death from heart attack and stroke 2 times in men and 1.6 times in women aged 65 years and older. Smoking also causes lung cancer, COPD (chronic bronchitis and emphysema), impotence, osteoporosis, poor circulation, and various other cancers.

Benefits of quitting smoking

If you quit smoking, your chances of dying from heart attack and stroke will be reduced to those who had never smoked. Additionally, it will also help reduce your chances of getting other health risks associated with smoking, improve your quality of life, and save you a substantial amount of money for a comfortable retirement—good health and good life.

Yes, you can quit smoking. With the help of your health care team you can quit cigarette smoking. Some people quit smoking very easily while others might find it difficult to quit. *If you have tried in the past and have not been successful*, *you are not alone. Most people make repeated quit attempts before they can successfully quit. The key to success is keep trying until you quit.* Different medicines are available to help you quit smoking.

continued

If you are willing to quit smoking (Anderson et al 2002)

- Set a quit date 2 weeks from today.
- Start cutting down the number of cigarettes you smoke daily.
- Ask your family and friends to support you in quitting.
- Ask your spouse or friend to quit with you.
- Remove all tobacco from your house, vehicle, and work place.
- Abstain from alcohol.
- Keep track of triggers of smoking and plan to overcome them.
- Join a support group (family, friends, or others); replace your smoking partners with nonsmoking partners.
- Replace your cigarette smoking routine with something healthy.
- Call our office if you have any problems or concerns. We can help.
- Focus on the healthy food choices and regular physical activity to prevent any weight gain.
- On the quit date, quit completely. Not even a single puff.
- Use nicotine replacement products as directed.
- Use smoking cessation prescription medication as directed.
- Keep your follow-up appointment in 2 weeks.

Goal:…… **My quit date is:**…….

I make a commitment to a healthy lifestyle. Patient Initials……. Date…….. Physician initials…….

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