done. A precipitous plunge into vigorous physical activity invites injury and disillusionment. On the other hand, a modest increase in physical activity performed by sedentary individuals will improve the overall health of our society more than increases in physical activity by those who are already active (*4*). The goal is to get everyone to be active. Marathons are not for everyone, but walking around the block probably is.

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Physical Activity Research and Coronary Heart Disease

An ounce of prevention is worth a pound of cure.

In the last few years this old adage seems to have gained renewed life and interest, especially in medicine and with regard to chronic diseases. However, the *informed* application of this maxim has not proven to be easy. Primary prevention of coronary heart disease (CHD), chiefly through nonpharmacological approaches, is an excellent example. Within this area of scientific interest the role of physical activity has been examined in a variety of settings and can serve as a model of more general problems.

Numerous carefully executed, prospective, observational studies have generally, if not consistently, identified several individual characteristics that relate to the subsequent development of CHD. These include the well-publicized and treatable risk factors of blood cholesterol, blood pressure, and cigarette smoking. However, subsequent research efforts to establish whether such risk factors are causative in the development of CHD or are simply correlated with CHD, possibly through some other factor, have been difficult undertakings. The knowledge base regarding the association between physical activity and CHD is not as well developed as for blood cholesterol, blood pressure, and cigarette smoking for several reasons, not the least of which is that exercise does not appear to be as important an independent risk factor as the others. Nonetheless, it deserves careful evaluation. Major aspects of the currently available information are discussed in considerable detail in this issue of *Pub-*

lic Health Reports in the papers from the Workshop on Epidemiologic and Public Health Aspects of Physical Activity and Exercise. They merit careful reading.

I would like to briefly highlight a few areas that, although reviewed in these papers specifically for physical activity and exercise, are generic problems.

• *Risk factor specification.* What is the important dimension of exercise to be studied with regard to CHD? Is it the *level* of routine physical activity or exercise? If so, do the type and intensity matter? Or is fitness the critical factor, however attained? Similar questions for blood pressure have been raised in the past. What is the most important variable? Is it systolic, diastolic, or mean blood pressure? How should it be measured—singly or as an average of several measurements or some form of integration derived from a 24-hour recording?

• *Use of observational data.* Most studies that have investigated the role of physical activity in the development of CHD in people have been observational rather than interventional. The persons enrolled in these studies maintained or modified their initial activity levels on their own, and did so for diverse reasons. They were then observed, usually over several years, for the onset of specified CHD events, with the relative frequency of these events calculated for different levels of activity.

As a general rule, observational studies only support conclusions that two variables are correlated, not that they are related to cause and effect. However, observational studies can support cause and effect relationships when multiple, carefully performed studies show the association to be consistent, strong, graded, temporally appropriate, independent, predictive, and coherent. They require careful planning; meticulous execution with simultaneous measurement of multiple, potentially confounding variables; careful analysis of the collected data; and cautious interpretation of the results from a single study. Obviously, similar study designs were used with other CHD risk factors. The causal association between smoking and CHD in humans has been accepted on the evidence from observational studies. Data from observational studies repeatedly showed an association between CHD and blood pressure and blood cholesterol before large multicenter clinical trials, such as the Hypertension Detection and Follow-Up Program, with 10,940 participants, and the Lipid Research Clinic's Coronary Primary Prevention Trial, with 3,806 participants, were undertaken. The currently available observational studies provide early support for the hypothesis that physical activity and risk of CHD are causally related.

• *Treatment crossovers in clinical trials.* Randomized, controlled clinical trials in physical activity or exercise have been conducted mainly for secondary rather than primary prevention. Although this study design can directly evaluate cause-and-effect relationships, it still presents several methodological problems of its own that in fact have made the adoption of this design problematical, especially for primary prevention. In the example where persons in a relatively inactive group agree to be assigned randomly to either a physically active, usually regular exercise group or to a continued physically inactive control group, two interesting problems can arise. First, it can be difficult to get the intervention group to adopt consistently a higher activity level for the prolonged period of time necessary for the study. Second, it can, almost paradoxically, be equally difficult to keep the control group, or at least a significant subset, from crossing over—that is, increasing their activity level to that of the intervention group, frequently because the general population is adopting a more active lifestyle.

The problem of crossovers clearly arises with most clinical trials, but most notably with regard to lifestyle interventions such as physical activity, cigarette smoking cessation, or diets to lower the number of calories or the amount of saturated fat or sodium intake. As a consequence of these crossovers between treatment groups, as well as other problems, sample size calculations using CHD endpoints yield large estimates that are generally viewed as not feasible, resulting in either inaction or smaller, less definitive studies. However, careful selection of either a high-risk population or an easily observed large population, or improved approaches to minimize the number of crossovers, may make such an intervention trial doable. Finally, preservation of the randomized design requires that the analysis be based on the original treatment assignment and not on the self-selected, actual behavior of the individual participants after randomization.

• *Confounding variables.* A physical activity intervention program can have beneficial effects on other important risk factors such as obesity, blood pressure, blood cholesterol, or cigarette smoking.

Consequently, even if the program is shown to be therapeutically effective, it will be difficult to isolate the effect to the physical activity itself as opposed to its effect on one or more of these intermediate variables. From an individual or even a public health viewpoint, this appropriate ascribing of effect may not seem or actually be terribly relevant, at least in the short term, while other more specific information is being gathered. But if, for example, an effect of physical activity is conclusively demonstrated and later shown to be due to its effect on serum cholesterol or some other risk factor, then more direct or adjunctive approaches to these "intermediate" variables would be appropriate if they were available. One of the current appeals of physical activity is that for many people it can be the most effective way to modify several other risk factors simultaneously.

• *Implications for clinical practice.* Even though the current knowledge base has important limitations, such as the nature of the physical activity presumed to be helpful and the absence of data on the effect of taking up exercise later in life, many practitioners recommend a regular exercise program for their inactive patients, particularly for those patients who are overweight or have other specific clinical problems. Although some concern remains regarding the risks associated with such a program as well as uncertainty with regard to the CHD and other benefits, many still feel that it is prudent to adopt such an approach. Obviously, based on further information, this approach may well have to be modified. In the past, similar active positions have been taken toward other risk factors such as high blood pressure and cigarette smoking. As more definitive information accumulated, the prudent approach of modification of these factors evolved into the accepted norm of practice.

• *Implications for public health.* Many experts have felt that the information base is not sufficient to support the argument encouraging population-wide adoption of increased physical activity solely for the purpose of preventing CHD. Nevertheless, even though not yet definitely proven, the role of physical activity in preventing CHD is sufficiently attractive and plausible when combined with other potential benefits that the Public Health Service has declared physical fitness and exercise to be 1 of 15 priority areas in which improvement is expected to lead to substantial reduction in premature morbidity and mortality. Simultaneously, the Public Health Service has strongly recommended more research. The endorsement of increased physical activity for the public at large should not be construed as acceptance of our current limited knowledge. The study design limitations mentioned earlier and others have and will continue to make it difficult to establish a causal relationship between this lifestyle intervention and CHD. Data from observational studies and other experimental designs should continue to be carefully collected and analyzed so that eventually a consensus could develop that might (*a*) recommend the initiation of a single or perhaps multiple intervention trials to finally resolve the question or (*b*) recommend the rejection or unqualified acceptance of the primary preventive and therapeutic value of this intervention without the need for large randomized intervention trials.

Thus, more research is needed. One of the difficult tasks is to decide which areas should be addressed first and with what study designs. The information assembled and reviewed in this issue of *Public Health Reports* provides some assistance. At the end of each paper is a list of suggested high priority research topics. The papers presented here as well as similar related efforts should help us all in making these important judgments.

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LETTER TO THE EDITOR

Asthmatic Students' Program Materials

RE: the Special Supplement: Winners of the Secretary's Award for Innovations in Health Promotion and Disease Prevention in the November-December 1984 issue of *Public Health Reports*.

In the article, "A Program to Help Asthmatic Students Reach their Potential" (pp. 606–609), the American Lung Association of Alabama was cited as the vehicle for the utilization and distribution of the program.

Due to a copyright dispute, the American Lung Association of Alabama will not market the program.

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