

# The Cost of Preventing Diabetes

## What do we know and what do we need to know?

The landmark Diabetes Prevention Program (DPP) demonstrated that we can prevent diabetes (1). The DPP study in this issue of *Diabetes Care* (2) presents the costs of that intervention. The challenge is how to implement those findings in real-world clinical practice settings. I will first provide a framework for thinking about a cost study and then comment more specifically on the findings.

Randomized clinical trials (RCTs) answer the first important question—is an intervention efficacious? That is, can it work? RCTs are carefully structured to optimize the opportunity to demonstrate that an intervention can work; hence, they are conducted in relatively idealized environments. Patients are carefully identified, not only for their clinical characteristics, but also because of their willingness to participate as subjects. Institutions with strong research and clinical support environments are selected to ensure that interventions are delivered as optimally as possible to enhance the likelihood that any real effect will indeed be found. If the trial demonstrates efficacy, we have proof of concept. Yet, we know that simply showing that there is an efficacious strategy is insufficient. Translating those findings into routine practice is a critical and daunting challenge. Only 25% of hypertensive patients have their blood pressure controlled despite over a quarter of a century of concerted effort. Thus, showing that interventions can work is simply not enough.

The questions we really want answered concern not the efficacy of an intervention, but its effectiveness—how well does intervention work in practice? What is the balance between its benefits and harms? These issues require an understanding of the barriers to implementation and the development of appropriate systems and incentives to ensure delivery of and adherence to regimens on the part of providers and patients.

One of the potential barriers is cost or, more particularly, documentation that

the benefits justify the costs. The DPP Research Group begins to answer that question by analyzing the costs of the DPP intervention itself (2). In cost studies, it is important to recognize which costs are and are not included, since such studies can be conducted from multiple perspectives and have multiple users (3). Costs are generally divided into direct costs, indirect (productivity) costs, and intangible costs. Direct costs are further divided into direct medical costs and direct nonmedical costs. Direct medical costs are incurred for the delivery of clinical services, such as office visits, hospitalizations, and medications, and health programs, such as education programs, and are usually borne by the health care and public health systems. Direct nonmedical costs, such as transportation costs and the value of the time used for care, are generally borne by the patient.

Indirect costs are the value of changes in productivity in the work force or the value of non-work time that is valued by individuals and employers. Intangible costs are the economic value of grief, pain, suffering, and other difficult-to-value costs of concern to individuals and families. Although a societal perspective would include all of these costs, in practice most cost analyses, particularly those conducted from the health care system perspective, limit themselves to direct medical costs. Most cost analyses do not include intangible costs, although when quality-adjusted life years (QALYs) are used as the outcome of a cost utility analysis, some intangibles are included in the denominator. The DPP cost analysis includes direct medical and nonmedical costs as well as indirect costs.

A cost analysis is a critical first step in conducting other types of economic evaluations, cost effectiveness (cost per unit health outcome, e.g., cost per life year saved), cost utility (cost per QALY), and cost benefit (net cost, where health outcomes are converted into dollars) analyses, which look at costs as well as health outcomes. Cost effectiveness analyses use

a time horizon that is long enough to capture all of the costs of an intervention as well as all the costs associated with the long-term health effects (both benefits and harms). When performing economic evaluations, the costs are generally combined with the health outcomes to help ascertain whether the net health benefit (benefits less harms) warrants the costs and also to provide insight as to how one can gain efficiency by improving the benefits or reducing costs (4). For example, targeting higher-risk patients may increase health benefits relative to costs, or more efficient delivery of services might reduce costs. While we can gain substantial insights from a cost analysis, such as the one in this issue of *Diabetes Care*, a fuller analysis would examine the effectiveness in real-world clinical practice and the long-term health outcomes as well as their costs.

One of the strengths of a cost analysis done within a clinical trial is the ability to get good estimates of the resources actually used and to value them. While within-trial costs may differ from costs in actual practice (they are usually higher because of more intensive follow-up and sometimes more resource-intensive medical care settings), the cost analysis of the DPP provides valuable insight into what those costs might be. The investigators have provided us with detailed resource and cost estimates for each of the major cost components.

So what can we learn from the cost analysis of the DPP? First, the annual direct costs of the metformin and lifestyle interventions averaged \$1,000–1,400 more than the placebo group the first year and was then approximately \$700 more per year thereafter. Some of those costs were offset by \$90–140 savings in direct medical costs. The cost of identifying patients with impaired glucose tolerance (IGT) and the interventions was less than half the direct medical costs for the 3-year period of the study. All of these costs would be borne by the health care system, and, viewed by itself, the cost of the inter-

vention to the health care system appears reasonable. Since the lifestyle intervention was the most effective strategy for preventing diabetes, it would appear to be the preferred approach. Compared with the cost of the less effective metformin arm, the direct costs of the lifestyle intervention seem modest. Yet there are at least three important barriers to delivering these services within our current health care system. First, the intensive behavioral services are not generally available in most primary care practice settings, and the organizational and human infrastructure to deliver these services is sorely needed. Second, and undoubtedly related to the first, few health care plans provide reimbursement for lifestyle interventions. We know that at least in the general population, behavioral counseling in the primary care setting, without intensive systems for follow-up and management, has not been shown to be effective (5). Third, helping people understand the benefits of healthy lifestyles is much easier than actually having them make healthy choices consistently. In fact, recent information tends to suggest that we are actually moving in the wrong direction (6). These barriers need to be addressed.

The direct nonmedical costs of the DPP include the time costs in seeking and receiving care as well as the value of time actually exercising. These costs are highly sensitive to the hourly cost used for physical activity. The dollar value of leisure time is particularly difficult to assess. The authors value leisure at half the hourly wage rate and, in a novel approach, fur-

ther adjust the value based on whether individuals like or dislike to exercise. Thus, those who like to exercise have a lower "cost" for each hour they exercise. Interestingly, individuals in the lifestyle group were more likely to enjoy exercising and a better quality of life; perhaps paradoxically, then, the "cost" of their exercise was relatively reduced.

Although this study provides some preliminary evidence that the costs of the DPP interventions are reasonable, we need to know the other side of the equation—the long-term health and cost impact. The appropriate next step is to develop decision models that look at longer-term time horizons, adjust for adherence, and examine the long-term health consequences, including changes in quality of life. We know that lifestyle changes can have a substantial impact on health (7). Improving our understanding of the best strategies to promote long-term acceptance of such changes cost-effectively is critical for reducing the growing epidemic of diabetes and associated disorders. An analysis using DPP data that summarizes all of the costs and all of the benefits and harms over time will provide health care and public health decision makers with a clearer understanding of the value of these interventions and will lead to policies that enhance the prevention of diabetes.

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