The Cost-Effectiveness of Preventing Diabetes

There are many hurdles in the adoption of preventive programs. The first is efficacy, demonstrating that an intervention can work, at least in optimal settings. The breakthrough Diabetes Prevention Program (DPP) easily cleared this hurdle (1). The next step is to show that it is effective, proving that the results can be achieved in usual-care settings with their resource constraints and often broader cross section of patients. The final quantitative hurdle is cost-effectiveness, showing that the intervention is worth its cost (2).

The economic evaluation by the DPP Research Group (3) in this issue of *Diabetes Care* is an excellent example of a well-done, within-trial, cost-efficacy study. Building on the group's earlier cost analysis (4), they use the numbers needed to treat (NNT) and utility analysis results from the trial to determine cost-effectiveness from societal and payer viewpoints. Within-trial analyses such as this one have several strengths. Costs and outcomes can be ascertained with a high degree of accuracy. Few assumptions and extrapolations are required. Yet within-trial analyses have limitations as well. Because of their limited time frames, important long-term costs and outcomes cannot be ascertained. We can only speculate about how well patients adhere to the regimens in the long term, whether the reductions in progression of disease persist (or increase or decrease), whether we are preventing or delaying diabetes onset, and to what extent major outcomes, such as cardiovascular events, and their associated costs are averted. Thus within-trial analyses capture only a snapshot of what we want to know and only part of the information required to determine the value of the intervention. To extrapolate beyond trials requires models with their assumptions and uncertainties. One would anticipate that improvements in lifestyle would have many health benefits other than those due to reduction in diabetes complications. In particular, reductions in cardiovascular events, blood pressure, osteoporosis, and certain cancers are not captured here and all should augment the overall value of improving physical activity and of weight reduction. Nonetheless, within-trial analyses provide a firm basis for further analyses.

Effectiveness is usually lower than efficacy since patients in the real world cannot be carefully selected and specialized resources are generally more scarce. The decrease in effectiveness may be disproportionate to the decrease in cost, hence cost-effectiveness is often poorer than cost-efficacy. Thus within-trial analyses often give us a "best case" scenario.

NNT has become more widely used as a tool in economic evaluations. It is intrinsically understandable by clinicians and can conveniently be combined with costs to calculate cost-effectiveness. Because it only measures a single outcome (new cases of diabetes in this study), other outcomes (long-term consequences of diabetes or harms of an intervention) are not captured. In addition, NNT intrinsically refers to a specific period of time, e.g., the NNT to avoid an adverse outcome over a 2-year period, and may therefore not capture longer-term benefits. To avoid these problems, the authors have also included a cost-utility analysis that uses quality-adjusted life-years (QALYs) as the outcome. QALYs assess changes in quality of life as assessed by patients and length of life. The limitation, of course, is that it is often difficult to link the intervention to the change in quality of life over a short time frame. Some of the difference in utility among the groups is no doubt due to the sense of well-being associated with physical activity and diet and only to a lesser extent due to the actual cases of diabetes prevented. Thus these two measures provide complementary assessments of the value of the interventions.

Importantly, the study included two perspectives. The health care system perspective includes only those costs it incurs. The societal perspective includes all those costs, plus all of the costs incurred by patients, their families, employers, and others. In this analysis, the direct nonmedical costs were greatest in the lifestyle group primarily due to participant time costs and to a much lesser degree by costs for fitness and dietary services and equipment. The indirect costs (time lost from work, school, or usual activities) were highest in the metformin group and lower in the lifestyle group than in the placebo group. The intangible costs and benefits are primarily captured in the denominator (QALYs).

As implemented in the DPP, from a societal perspective, the cost-effectiveness was $51,600 and $99,200 per QALY gained for the lifestyle and metformin groups, respectively, and $28,700 and $35,000 from the health system perspective. In general, interventions that cost over $100,000 per QALY are considered expensive, and those under $50,000 per QALY are considered reasonable. Thus both interventions can be considered moderately expensive from the societal perspective. Indeed, both interventions provide benefit but also increase health care cost.

The sensitivity analyses allow us to gain a better understanding of the important cost drivers. Reduction in personnel costs markedly reduces the cost in the lifestyle group and reduction in the cost of metformin, e.g., by the availability of generics, markedly improves the cost-effectiveness in that group. Whether the effectiveness of the lifestyle group can be maintained with more efficient interventions, such as the group sessions proposed by the authors, will become a critical question in enhancing the feasibility of implementing a widespread program.

In our technology-driven health care reimbursement system, reimbursement for behavioral interventions sadly lags behind reimbursement for other clinical services. Payers need to provide reimbursement for these critical services, particularly for these high-risk patients. With the obesity epidemic and minimal progress in improving physical activity

and diet, population-based interventions targeting these conditions will need to be enhanced by the delivery of sustained clinical interventions to maximize their impact if we are to address the burgeoning epidemic of chronic disease, of which diabetes is a part.

Quite clearly, the lifestyle intervention is more cost-effective than the metformin intervention, and the long-term benefits should be greater than those found within the trial. For those unwilling or unable to make the requisite lifestyle changes, the metformin intervention is a viable alternative. Insurance coverage for the lifestyle intervention would remove an important barrier to participation. Not only would it make it more feasible for patients, but adequate coverage would also allow providers to develop the infrastructure to provide these services.

STEVEN TEUTSCH, MD, MPH

From Merck and Co., Inc., West Point, Pennsylvania.

Address correspondence to Steven Teutsch, MD, MPH, Outcomes Research and Management, Merck and Co., Inc., P.O. Box 4, WP 39-168, West Point, PA 19486. E-mail: steven_teutsch@merck.com.

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