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Evaluating the Costs and Benefits of Outpatient Diabetes Education and Nutrition Counseling

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The Board of Directors of the American Diabetes Association (ADA) recently endorsed a resolution recommending third-party payment for outpatient education and nutritional counseling. One of the major rationales for the statement was that education and nutritional counseling will lead to reductions in health care costs. This article critically reviews the 13 studies cited in support of the ADA Policy Statement. Among these studies, only 2 compared a treated group with a control group. Both of the studies with control groups failed to randomly assign patients to treatment condition. Only 4 of the studies showed an accounting of program costs. Upon close inspection, it appears that some of the programs actually increased, rather than decreased, health care expenditures. Attrition from programs was reported in only a minority of cases, and was large when reported. The effect of the programs upon diabetes control was inconsistent across studies. It is suggested that the rationale for education and nutritional services be based on improved health status. In addition, the execution of a systematic experimental study to evaluate these services is urged. DIABETES CARE 1986; 9:81–86.

In June of 1983, the American Diabetes Association Council on Education, Health Care Delivery, and Public Health issued a resolution concerning third-party reimbursement for outpatient education and nutritional counseling. The resolution asserts that the American Diabetes Association (ADA) supports and encourages reimbursement for these services. In addition, the resolution asks members of ADA to take all possible measures to make such coverage available and accessible to patients with diabetes. The resolution was adopted by the Board of Directors of the American Diabetes Association on June 9, 1984.[1]

It is widely believed that education and nutritional counseling lead to a reduction in health care costs. The policy statement argued that "studies have shown that education and self-care programs lead to reductions in hospital days and associated costs." Thirteen references were cited to substantiate the suggestion that educational and nutritional services will reduce health care expenditures for patients with diabetes.[2–14] While resolutions of this type are understood to be more politically motivated than an indication of new research findings, we felt compelled to examine the evidence upon which this resolution is based. In this article, we review the methodologies for the cited evaluation and research studies and consider the scientific basis for the belief that outpatient education and nutritional counseling services reduce health care costs.

Among the 13 reports cited in the policy statement, one[13] was a second report of a study previously cited,[14] and others were multiple reports of the same program (see refs. 8 and 10 and refs. 9 and 11). Thus, we found 10 original reports relevant to the conclusions. A summary of 12 reports (excluding the one report that merely summarized another citation) is presented in Table 1. The table summarizes each study, describes the population, the presence of a control group, the outcomes, the costs, and notes other variables such as attrition and characteristics of patient assignment. Issues relevant to these studies will be discussed under the headings: Study Design, Cost Reductions, Length of Follow-up and Attrition, and Extrapolation of Results.

STUDY DESIGN

It is widely accepted among medical and biobehavioral scientists that a control or comparison group is required to establish causal inference. In some cases, scientists are willing to accept "quasi-experimental" data in which an ad hoc control is used or where there is a stable baseline of observations prior to an intervention. However, several authors have ar-

gued that an experiment characterized by a single observation, an intervention, and a second observation is virtually impossible to interpret from a causal perspective.[15]

For experiments using control groups, random assignment to treatment and control conditions is very desirable.

Several recent reviews have documented that there are many sources of bias in studies that do not randomly assign patients to treatment and control conditions. Failure to use strict randomization and blinding procedures typically results in overestimates of the effects of the therapy under study.[16,17]

Among the reports summarized in Table 1, only two[3,5] reported any control or comparison group. In those two cases, patients had not been randomly assigned to treatment or control groups. Since no study involved the random assignment of patients to experimental or control groups, none of the studies summarized in Table 1 adequately addressed the issue of decreases in service demands as a function of the program.

PROGRAM COST ACCOUNTING

Several factors influence the cost of a program. There are direct costs associated with the medical treatment, costs of health providers, medications, or special diets. There are also indirect costs associated with travel to the health care provider, time lost from work, etc. Russell[18] has argued convincingly that cost-effectiveness analysis should take a social perspective. According to this strategy, cost accounting must consider all costs and effects of the program, regardless of who pays for them.

Some of the cited programs only consider the effect of a program on hospital charges. Yet, programs themselves have

TABLE 1
Summary of studies

Study	N	Population	Control group	Random assignment	Program description	Physiologic outcomes	Costs		Attrition	Notes
							Medical care*	Savings†		
Jacobson et al.[2]	Not given	Military patients at internal medicine clinic	No	NA	15 h of instruction in self-care by clinic nurse	Not reported	Not reported but clinic visits and medication use went up	Decrease of hospital admission and 1 day decrease in length of stay	Not reported	Average length of stay went from 15 to 14 days
Runyan[3]	Treatment = 1006; control = 498	Memphis clinic patients with diabetes, hypertension, or cardiac disease, or combinations	Yes	No physician assigned; criteria not given, controls older, study group had more hospital days and poorer control	Compares a decentralized clinic with detailed follow-up to conventional, hospital-based care. Nutritional and counseling services not described	↓ Blood glucose	Not reported. Home visits and professional contacts went up in treatment group. Clinic visits went down in control group	Hospital days went down in study group and up in control group. Both regressed toward mean	Not reported	Study group had 2.6 times as many hospital days before study. Could be a regression effect
Miller et al.[4]	557 from Runyan study	Same as Runyan	No	NA	Same as Runyan	Random blood glucose went down first 3 yr then increased each of the next 4 yr	Not reported	Hospital costs down 53% in comparison to year before referral	19% died 26% lost to follow-up	Changes for each year of study representing selective attrition
Spaulding and Spaulding[5]	13 treatment, 13 comparison	Juvenile and adult diabetic patients	Historic with correct sex match on only 5 of 9 juveniles	No	Initiation of insulin therapy in outpatient versus hospital settings	Pretreatment differences favoring comparison group (difference = 10% mg/dl)	Included lab costs, physicians' fees, nursing costs, nutritionists' costs (versus) costs of hospital program	Differences between two program costs	No follow-up	Greater decline in blood glucose for hospital patients. However, blood glucose values for adults measured at different times. Blood glucose only measured for 3 juveniles in day-care group
Whitehouse et al.[6]	89	Clinic population insulin-requiring	No	NA	5 daily classes for patients and families (including advice on nutrition). Return visits at 10 days, 4–6 wk, and 6 mo	(a) Decrease in fasting plasma glucose after 5 days (b) Decrease in HbA_1 after 6 mo (c) No change in body weight (d) No change in lipids	Costs include personnel, supplies, lab charges, and indirect costs (patients spend 5 full days in class)	Based on estimate of 5-day hospitalization instead of program	17 dropouts	This is a hospital-based program in which patients go home at night

TABLE 1 (continued)

Study	N	Population	Control group	Random assignment	Program description	Physiologic outcomes	Costs		Attrition	Notes
							Medical care*	Savings†		
Beaven et al.[7]	Not reported	Christ Church Diabetes Center, New Zealand	None	NA	1 morning/wk for 4–5 wk discussion group of 12–20 people. Tutorial for poor performers	Claims significant gain in knowledge and decrease in blood sugar. Methods or values not reported	Not reported	↓ Hospital occupancy by diabetics 14% 1977 and 11% 1980	Not reported	Program description without data, not a formal study
Davidson et al.[8]	Program serves 8000 diabetic adults	Grady Memorial Hospital–Inner City, Atlanta (82% Black)	No	NA	Comprehensive program includes specialty clinics, hospitalization for severe cases, nurse clinics, postgraduate training	Decrease in hospitalizations, reduction in use of oral agents, improved blood glucose, fewer amputations, increased patient satisfaction	Not reported. Patient clinic visits increased 5.4 times	Reduced hospitalizations, amputations, medicine costs	Not reported	All patients with high blood glucose (>500 mg/dl) admitted as inpatients. Cost impact of these admissions not noted
Miller et al.[9]	Not given	Large indigent population served by an inner-city, 2200-bed teaching hospital	No (some comparison with non-clinic patients)	NA	Included hot-lines, walk-in clinic, triage system of training nurses, information (chart) retrieval system	Not given	Not reported	Reduced hospital admissions	Not reported	Results from self-selected patients at one hospital extrapolated to 10 million American diabetic patients
Davidson et al.[10]	1221 patients 127 completed follow-up	Grady Memorial Hospital–Inner City type II patients	None	NA	Intensive diet-therapy program including 1-wk fast	No change random blood glucose 7 yr after stopping oral agents. Wt loss (as % ideal) 145.5–127.4%	Includes salaries, meals, materials, and book	Oral medications and insulin costs. Hospital costs DKA amputations	90% loss of initial 1221 patients to 127	Difficult to interpret because of 90% attrition rate. Selective loss to follow-up can lead to overestimate of treatment benefit
Miller and Goldstein[11]	Not given	L.A. County USC Medical Center diabetes section patients	None	NA	(1) Telephone answering service (2) Policy to screen candidates for admission by nurse or FO in diabetes section	None reported	No details $20,350.00 (grant funded)	Annual admissions decreased from 2680 (1968) to 1250 (1970) and # days in hospital/patient decreased	NA	Basically a triage system designed to decrease admissions. Link to ADA policy on nutrition and educational counseling not obvious
Merritt et al.[12]	108 patients of initial 254	Malcolm Grow USAF Medical Center	None	NA	2½-h class weekly for 4 wk	↓ 2 h fasting blood glucose ↓ weight. Wt loss correlated with blood glucose change	Not given. However, staff included physician, medical pharmacist, dietitian, diabetes teaching nurse, and podiatrist	No change admissions for uncontrolled DM with ketoacidosis ↓ in admission for uncontrolled DM without DKA	254 started 108 completed the course	Large attrition rate. No overall effect on hospital admissions. Staff intensive program
Maine Diabetes Control Project[13]	553 diabetic patients	Participation in Maine Control Project at 26 sites	None	NA	Detailed outpatient education programs were developed at each site consistent with state guidelines	Not reported	Accounting of program costs available. But, based on estimated hours and salaries (e.g., dietitians and nurses are estimated at $7.00/h)	39.8% in hospitalization (based on 46 patients)	553 started 461 completed	Attrition from 553 to 461 patients. Estimate cost at low rates. Estimated savings at hospital rates

NA, not applicable.
*Costs of program; †acute medical care, costs of hospitalization, institutionalization.

costs. It costs money to employ dietitians, counselors, physicians, and to create educational material. Extra health care requires extra expenditures. Some of the studies cited in the ADA policy statement actually seem to show increases in health care costs. For example, in the widely cited paper by Runyan,[3] clinic visits went down as a function of a program, but home visits and professional consultations increased. The author accounted for the reduction in clinic costs, but did not account for the increases in expenditures for home care or for other program costs.

Only four of the studies reported an accounting of health care costs.[5,6,10,14] It is very difficult to determine whether these programs actually saved money since program costs are not included in refs. 5 and 6. Details in program accounting were often absent, with the exception of two reports.[10,14] No study performed a discount analysis, and it was common to leave net differences unreported.

Some of the studies simply failed to recognize that services are an expense. In one report[2] it was said that money could be saved by having a physician see more patients per day. These investigators increased the number of patients that a fixed-wage military physician treated by 35%. It was assumed that a physician would be paid a fixed hourly rate and thus the cost per patient would be reduced. By fitting more patients into the clinic schedule, it was assumed that money would be saved. However, services are usually reimbursed on a per unit basis. This program actually increased the number of physician visits. In other words, service utilization increased. On a per unit billing basis, costs would increase rather than decrease.

Cost accounting in some of the most effective programs has been particularly problematic. For example, the Grady Memorial Hospital in Atlanta has built an exemplary program. However, in one report[8] details of the program were described without cost accounting. The program includes several clinics, postgraduate education courses, hospital-based teaching for admitted patients, and many other services. In fact, all patients with plasma glucose levels exceeding 500 mg/dl are hospitalized for special education and evaluation. The availability of the program greatly increased patient utilization. Between 1967 when the program was begun and 1979, utilization of services had increased more than five times. However, creating these services added costs. The report of the program only noted that the program was paid for by the hospital, The Georgia Regional Medical Program, Emory University, or NIH grants. We cannot conclude that costs were reduced unless we know how much it cost to launch and operate the program. In other words, it is the net savings over discounted expenditures that truly represents savings.

INDIRECT EXPENSES

Programs rarely consider time costs for patients, although patient time is a resource. People can sell their time or use their time to make money. If they participate in a program, they must invest time that could be consumed in work, or sacrifice time that can be used to earn wages. They might also sacrifice recreational time that may be very valuable to them. Patient time costs are often ignored because it is difficult to trace them as dollar expenditures.

A program that reduces health care utilization by increasing contact with nontraditional providers does not necessarily save money. For example, in a preventive program an educator may see a large number of patients and bill for each one. If successful, the program will avert expenses in some fraction of these patients. Thus, there is a current small expenditure on a large number of patients to offset large later payments for a subset of these patients. This may also shift costs so that they are reimbursed differently. In this case the preventive provider is reimbursed now in exchange for the tertiary provider being reimbursed later. Cost shifting is not necessarily equivalent to cost reduction.

Perhaps the best and most influential report in the literature was the Maine Diabetes Control Project, which was completed in November of 1983. This report evaluated a small sample of 99 patients who had 395 hospital days (nearly 4 days per patient!) in the year before the study. In this study, averted hospital charges were used to estimate the benefits of the program. However, on the program cost side, an administrative perspective was used. In the analysis, education costs were estimated below market rates. For example, the cost for a nurse educator was estimated at $7/h. Individual (1 to 1) dietary instruction sessions by a registered dietitian were presumed to cost $7/h. Even if these well-trained providers were paid only $7/h, charges to patients would usually be higher. One must consider preparation time, missed appointments, and employee benefits in defining provider wages. If patient charges are $7/h, the provider wage might be one-half this amount. One wonders whether highly trained professional providers would be willing to deliver professional services for this rate.

None of the studies cited in the policy statement considered any indirect costs to the patient. No study considered costs of travel time or changes in diet. In addition, none of the studies considered cost to the patient in terms of lost work, etc. Only one study reported the costs of medications and one noted costs of patient education materials.

Cost-effectiveness analyses are very sensitive to assumptions about alternative uses of money. In the cost-effectiveness literature, this is known as the "discounting problem." Preventive programs are particularly sensitive to discounting assumptions.[18] If we are purchasing a future benefit, we must discount or value the benefit at the rate the money is expected to be worth at the time the benefit is delivered. If money is spent on education and nutritional counseling in order to reduce hospitalizations 5 yr hence, the analysis must discount the benefit by a figure that approaches the inflation rate. Since current dollars can be used to purchase acute care, discounting recognizes that current funds will have a different value at the time the benefit occurs.

LENGTH OF FOLLOW-UP AND ATTRITION

Another issue is the length of time that an educational benefit lasts. It is often assumed that patient education courses result

in changes in patient behavior that last over an extended period of time. Yet, in diabetes care it is not well established that patient knowledge and patient behaviors are correlated.[19] Furthermore, many studies have shown rather disappointing long-term effects of educational and behavioral programs. For example, Foreyt et al.[20] argued that studies on weight reduction rarely followed the patients for longer than a few months. Among those studies reporting 1-yr follow-up data, the effects of interventions for weight loss tended to be disappointing. Wing et al.[21] have reported the only randomized trial of nutritional counseling with >1 yr of follow-up. They failed to observe a long-term treatment benefit.

Consideration of the length of benefit is very important in cost-effectiveness studies. Some interventions may be very effective because they require a single administration of a vaccination. However, when carefully analyzed, other preventive programs have not always been found to be cost effective. Preventive programs often require the gradual expenditure of funds over an extended period of time. In the case of nutritional and educational counseling, it is presumed that some patients, even with ideal counseling, will still not change behaviors to the extent that they affect outcomes. In addition, only a fraction of those who receive the counseling would have been hospitalized had they not received it. Thus, some funds are expended on patients who may not necessarily require services. Finally, promoting adherence to recommendations in the counseling sessions may require expenditure of funds over an extended period of time. For example, improved adherence may require greater expenditures for food, medicines, monitoring supplies, etc. A proper analysis should consider all of these factors in relation to the expected change in outcome. All of these costs must be added to the costs of the services themselves to produce a meaningful evaluation.

Only five of the studies in Table 1 reported on the number of patients who dropped out or were not available to be followed. In nearly all of these cases, attrition was substantial. Thus, the possibility remains that there is selective loss to follow-up. Half the studies either report no follow-up or had no follow-up.

EXTRAPOLATION OF RESULTS

Another problem in several of the studies is the extrapolation of results. For example, one report[9] observed highly self-selected patients who utilized a specialty clinic. These patients were self-selected from among low-income, medically indigent residents of Los Angeles. They were compared with patients who decided not to use the clinic even though it was available to them. On the basis of observation of this single self-selected group of medically indigent patients, extrapolations were made to 10 million diabetic individuals in the United States. In other words, an estimate of cost savings to the nation was suggested on the basis of self-selected patients in one hospital. The number of diabetic patients used for the extrapolation would include those with varying levels of disease (most of them mild), many of whom may not require education services, and indeed, some who have yet to be diagnosed. Furthermore, this study neglected to consider the added costs to the health care system of creating a national system of delivery comparable to the one they described for their community.

If third parties are to reimburse for a *treatment*, that intervention should be well defined. Yet, programs cited in the policy statement differ greatly from one another. Some[2] involved instruction by clinical nurses. Others were very labor-intensive programs involving a wide variety of health care providers.[10] At the other extreme, some of the programs had little to do with diet and education. For example, Miller and Goldstein[11] used a telephone-answering service to discourage diabetic patients from using the emergency room. Although this program may have been effective, its connection to education and nutritional counseling is unclear.

In summary, accounting for costs is a difficult task. Russell[18] and others suggest that accounting should take a social perspective. At a minimum, to determine whether a program saves costs, one must evaluate the following: (1) the direct and indirect costs of the program, (2) the savings attributable to the program, and (3) net program benefits. It is important to show costs for all patients who receive service and to base estimates of treatment efficacy on experimental studies that have adequate follow-up. Discounting for future benefits should be applied to current benefits. These program benefits are often determined through an assessment of averted hospital or health care costs.

DISCUSSION

We do not intend to be negative with regard to the potential for lowering health care costs through educational and counseling services. In fact, we support such services and believe they should be eligible for third-party reimbursement. However, the criteria for the evaluation of education and nutritional counseling should be the same as those applied to other therapeutic interventions. First, we must have evidence that the interventions have a favorable impact on health status. Cost savings may be one criterion, but should only be considered in relation to the effectiveness of the treatment. As has been demonstrated with the DRG experience, length of hospital stay and rate of hospital admission can be affected by simple reimbursement strategies.[22] Whether these changes result in poor health outcome will be determined in future evaluations of the prospective reimbursement systems.

Clearly there is concern about the high utilization of hospital services by patients with diabetes mellitus. Furthermore, there have been convincing suggestions that many of the hospitalizations are preventable.[23] With the increasing cost containment pressures within health care, reduction in unnecessary and expensive hospitalizations should remain a high priority. In addition, we must recognize that the objective of care is not to reduce costs. Instead, we should focus on improving health. Nutrition and education counseling may help patients and should not be evaluated only as economic products.

In summary, patients with diabetes mellitus may overuse expensive hospital services. There is some evidence that educational and counseling services might produce a reduction

in hospital utilization. Such a reduction may result in considerable cost savings relative to the costs of the program. However, we currently have very little information on the effects of these services relative to their costs. Reports cited in a recent ADA policy statement do not meet widely accepted criteria required to establish the causal effect of a treatment. In addition, cost accounting was rarely performed to consider full program costs.

We believe there is substantial potential for improved health outcomes and decreased costs through educational and nutritional services in diabetes care. Yet, at present, there is no firm experimental literature upon which to base this inference. The funding and execution of rigorous scientific experiments in diabetes education should be encouraged.

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