

The Child, the Adolescent, and the Diabetes Control and Complications Trial

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In the November, 1993 issue of our companion publication, *Diabetes*, my friend and colleague Dr. Julio Santiago has written a thoughtful, informative, and provocative perspective entitled "Lessons From the DCCT." I strongly commend it to you.

My purposes in this commentary are quite different. Like Dr. Santiago, I have served as the principal investigator of the DCCT at my institution, The University of Pittsburgh. This clinical research project has occupied a central focus of my professional responsibilities for the past 10 years. It has been an extraordinarily challenging, frustrating, exhilarating, and exhausting experience. The answers are in, and they are clear and unequivocal—control matters. Now the really hard part begins. How do we implement the clear imperatives of the DCCT?

I am restricting my observations to the child and adolescent populations with IDDM, but hopefully the relevance can be generalized. But first, several aspects of the DCCT must be emphasized. The DCCT did not prove that multiple-dose insulin therapy decreased vascular complications. It did, however, clearly demonstrate that intensive diabetes management, conducted within a highly

structured research environment by highly motivated diabetes professionals and carefully selected and randomized patient volunteers, can lead to a significant reduction in the rate of development of the major vascular complications of diabetes.

It is tempting to jump to the conclusion that the beneficial results of this study were directly and fully related to the reduction in blood glucose and glycosylated hemoglobin that characterized the experimental group. This is unwarranted. The study randomly compared two total therapeutic packages. The "full-court press" of the experimental group is characterized by the ultimate therapeutic team, including the patient as the central member, the diabetes nurse educator, dietitian, behavioral scientist, and diabetologist. Team members were available 24 h a day, and therapeutic consultations occurred weekly with full clinic visits on a monthly basis.

Approximately 20% of the total DCCT cohort was in the 13- to 19-yr age-group at entry, with equal numbers in the conventional and experimental arms. Mean glycosylated hemoglobin and blood glucose levels were modestly higher in the adolescents in both groups compared with those who were between

19 and 39 yr of age at entry. Although many of the adolescents in the study presented especially challenging therapeutic problems, they did not "wreck the study," as many investigators initially feared. Further, we all learned that "adolescent irresponsibility and poor compliance" were not restricted to an age-group.

It is estimated that <5% of all patients with IDDM in the U.S. receive care from a diabetes specialist. Our extrapolations indicate that a somewhat higher figure, possibly 20%, of children and adolescents with IDDM have some therapeutic guidance through a university-based or diabetes specialty center where the therapeutic team is an integral component of management. Regardless of the exact statistics, the great majority of both children and adolescents with IDDM receive medical care from family practitioners, pediatricians, internists, and other physicians who have little specialized training or knowledge about current diabetes management. Few of these physicians or their patients have access to the multiple benefits of a diabetes therapeutic team.

I firmly believe that few physicians, whether specialists or generalists, have the expertise, resources, or time to provide quality total care for patients with diabetes. This disease requires teamwork. To me, this is one of the most important messages from the DCCT. Duplicating the DCCT intensive therapeutic program to more than a small fraction of the patients with IDDM in this country is currently impossible. The professional personnel are unavailable and the cost is prohibitive. How are we to proceed?

Recommendations for general policy implementation

1. **Develop regional centers of excellence in diabetes research and management.** Such centers should have leadership responsibilities for establishing effective working relationships with community hospi-

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DCCT, Diabetes Control and Complications Trial; IDDM, insulin-dependent diabetes mellitus.

tals, clinics, and private doctors' offices.

2. **Promptly expand training for nonphysician diabetes specialists and assist in their placement in local communities.** This must be combined with effective means for third-party reimbursement for the time and efforts of all the non-physician professionals involved in patient management.
3. **Improve and expand medical school education to enhance the development of physician team leaders in diabetes and other chronic diseases.**
4. **Develop effective ongoing educational opportunities for local physicians so they can keep abreast of changing diabetes therapeutics and integrate into local and/or university-based diabetes therapeutic teams.** We must more effectively use the special talents and resources of the local physician.
5. **Promote research to effectively identify barriers to treatment compliance and develop strategies to ensure adherence to management programs directed toward improved health.**
6. **Encourage patients and their families to become proactive in the local community and at the state and national level regarding political decision-making concerning health-care issues, particularly as they relate to diabetes management.**
7. **Continue to explore the application of computer-based techniques for patient education, monitoring, and physician/team therapeutic decision-making.**

Recommendations for individual patient management

1. **Embrace the DCCT results as an important means of improving**

the future health and well-being of our patients.

2. **Ensure that all patients have the advantages of a multidisciplinary therapeutic team.**
3. **Insist on frequent blood glucose monitoring and routine determination of glycosylated hemoglobin and use of this information to continually evaluate and alter therapeutic strategies to improve metabolic control.**
4. **Improve metabolic control slowly and deliberately.** The DCCT HbA_{1c} goal of 6.05% was rarely achieved and infrequently sustained. The mean of 7.2% achieved by the experimental group at the end of the study is a more reasonable initial goal (or its equivalent in other glycosylated methodologies) for the postpubertal adolescent. We must acknowledge the increased dangers of serious hypoglycemia and develop strategies to minimize its occurrence.
5. **Use the expertise of behavioral scientists to help both patients and professionals overcome barriers to compliance.** Behavioral disabilities as well as overt psychopathology are common complications of the adolescent with diabetes. These patients and their families deserve professional care.
6. **Reserve specific goals of near metabolic normality for the adolescent.** No patients younger than 13 yr of age participated in the DCCT. It is my personal feeling that although the philosophy of improved metabolic control should permeate all of our patient therapeutic relationships, regardless of patient age, these specific goals of near metabolic normality should be reserved at this time for the adolescent.
7. **Avoid hypoglycemia.** Despite the absence of evidence for CNS pathology as a consequence of hypoglycemia within the DCCT, this

danger cannot be dismissed, particularly in the younger child. All too often in the preschool-aged child, we are faced with problems of extremely erratic blood glucose variation and must make a therapeutic decision that leans toward either excessively high blood glucoses or increased frequency of hypoglycemia, with or without symptomatology. In my mind, avoiding hypoglycemia is always the correct decision, assuming that ketonuria and weight loss can be avoided.

8. **Ensure appropriate reimbursements for the contributions of the nonphysician professionals.** We all need time to "shake out the system" and discover what will and will not work in the real world of our clinics and offices. And just as important is determining what the reimbursement systems will bear. Increased frequency of patient contact and laboratory monitoring is obviously essential. Appropriate reimbursement for the contributions of the nonphysician professionals must be ensured nationwide.

The results of the DCCT challenge all of us to find innovative new approaches to bring the rewards of improved management to all of our patients. Despite the increasing chorus of "I told you so's," the fact remains that to function effectively, our therapeutic decisions must be firmly based on solid science. Until now, we could not honestly tell our patients and their parents that all of their efforts made a difference. Now, we have an exciting, hopefully motivating message to all of those afflicted with diabetes. Through teamwork, we must make intensive therapy real, available, affordable, and obtainable in the new, emerging era of health-care reform.