

Incorporating the Results of Diabetes Research Into Clinical Practice

Celebrating 25 years of Diabetes Research and Training Center translation research

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In our July issue, Dr. Roland Hiss presented the paradigm of the Michigan Diabetes Research and Training Center's (DRTC's) approach to the difficulties and opportunities of translating the results of clinical studies into clinical practice (1). As the DRTCs reach their 25th anniversary, it seems appropriate to review their progress in understanding and improving the translation of clinical trials into clinical practice. I have asked the coordinators of translation research of the six DRTCs to briefly summarize their approaches and successes in this area, which follow.

It is important to note that the DRTCs began in 1977 in an environment where we knew that there were huge gaps between the results of clinical trials and clinical practice, but we knew little about why those gaps existed, nor did we know how to close them. In large measure our progress in translation research and our successes in translating the subsequent landmark clinical trials into practice are and will continue to be a result of the research conducted by the DRTCs. All of the DRTCs have made vital contributions to this area of research. We present their experiences in alphabetical order.

University of Chicago
Marshall H. Chin, MD, MPH, Associate Professor of Medicine. The University of Chicago's DRTC Demonstration and Education (D&E) cores have focused on developing provider-, patient-, and systems-level interventions to improve the quality of care and health outcomes of diabetic patients, with a concentration on particularly vulnerable minority and low-income patients. Initially, the University of Chicago aimed to train health care professionals to deliver state-of-the-art diabetes care. To help disseminate these educational programs beyond a regional level, it initiated national collaborative efforts with the American Diabetes Association and the American Association of Diabetes Educators (2–4). For example, the American Association of Diabetes Educators published *Diabetes Update: From the Basics Forward*, which was a detailed program guide for group facilitators to conduct a 2-day workshop on the clinical and educational management of diabetes (5).

Although these programs directed at health professionals helped improve diabetes care, we recognized the importance of assisting patients to more effectively

manage their disease and their lifestyles. Special emphasis has been given to developing programs for minority and vulnerable populations, including African-Americans and Hispanics (6–8). Key to this effort has been exploring alternative means of delivering lifestyle modification programs through the use of lay group facilitators and health promoters. For example, the Pathways Lifestyle Modification Program for African-American Women is a successful weight loss program tested in a clinical setting and as part of a church-based lay educator program in inner-city African-American churches (9). In the latest study, 110 African-American women at high risk for diabetes were randomly assigned to either the Pathways program or to a control group. At the end of 14 weeks of active treatment, subjects in the Pathways group lost about 5% of their baseline body weight, whereas weight in control group subjects remained essentially unchanged. Weight loss was maintained for the full year of follow-up (10). The study demonstrated that a culturally relevant lifestyle program can provide significant weight loss in African-American women who typically do not benefit from such efforts. Second, it provided evidence that lay women can be trained to conduct successful lifestyle modification programs in their own neighborhoods (11).

Our most recent efforts use multifactorial interventions that simultaneously aim to improve the system of delivering diabetes care, educate providers and improve their skills in facilitating behavioral change, and empower patients to play a more active role in their care. Currently, we are collaborating with community health centers that serve the indigent population in the Midwest and West Central regions of the country, as well as locally in the city of Chicago. These health centers play a vital role in serving vulnerable populations and have particularly difficult challenges because of limited resources and poor patients (12,13). Many

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Abbreviations: CDC, Centers for Disease Control and Prevention; DCCT, Diabetes Control and Complications Trial; D&E, Demonstration and Education; DPP, Diabetes Prevention Program; DRTC, Diabetes Research and Training Center; EDEC, Educational Development and Evaluation Core; IU, Indiana University; MDRTC, Michigan DRTC; MDU, Model Diabetes Unit; VDRTC, Vanderbilt University DRTC.

of these efforts are in collaboration with the Health Resources and Services Administration's Bureau of Primary Health Care and draw on elements of continuous quality improvement (14), chronic care models of disease management (15), and behavioral change methods (16). Other recent health services research work by Chicago D&E core investigators include assessment of risk perception and treatment preferences of patients with diabetes (17), analysis of the care of older patients with diabetes (18–20), use of provider profiling and report cards to improve the quality of diabetes care (21,22), cost analyses of diabetes care (23–25), and the development of conceptual frameworks for approaching the care of older African-Americans with diabetes and the role of religion in diabetes care (26,27).

Albert Einstein College of Medicine Judith Wylie-Rosett, EdD, RD, Professor of Epidemiology and Social Medicine, and Elizabeth A. Walker, DNSc, RN, CDE, Associate Professor of Medicine and Co-Director of Prevention and Control. The early focus of the Albert Einstein College of Medicine DRTC's D&E component was on diabetes team development, with an emphasis on dissemination of medical and technological advances to multidisciplinary health care professionals. During the mid-1980s, the scope of this work expanded to address system barriers that prevented delivery of "ideal" diabetes care in various health care settings. The D&E cores supported important clinical research in hypoglycemia, counterregulation, and intensive insulin therapy in type 1 diabetes (28–30). The D&E cores also facilitated early research in blood glucose monitoring (31,32), which added to the knowledge base about this emerging technology for self management, including quality assurance. The Albert Einstein College of Medicine D&E team has collaborated in major clinical trials, such as the Diabetes Control and Complications Trial (DCCT)/Epidemiology of Diabetes Interventions and Complications (EDIC) and the more recent Diabetes Prevention Program (DPP), and contributed to behavioral aspects of the intervention and evaluation as well as the translation efforts for these studies. Thus, the D&E project themes have been at the patient, provider, and system levels, with barrier identification and problem solving for optimal diabetes care and outcomes in communities experiencing health dispar-

ities. A major lesson learned over the years has been the wide gulf between *awareness* and *sustained action* at each level in health care.

The Neighborhood Family Care Clinic (NFCC) Project (1988–1992) evaluated a program development/expert consultation approach in primary care clinics in medically underserved communities (33–36). The Dietary Intervention Evaluation of Technology (DIET) (1987–1992) project, which was also supported by the NHLBI, evaluated the use of videos and workbooks to optimize staff time in community-based weight control programs (37–39). With the Precede-Proceed Model for Health Promotion Planning as the heuristic, several projects were developed in the early 1990s to test patient-centered interventions to prevent or detect complications of diabetes. A collaborative project with the Centers for Disease Control and Prevention (CDC), Division of Diabetes Translation (1992–1995) evaluated methods for disseminating the CDC care guideline materials in community health centers (40). In the Ophthalmic Complications Prevention Trial (1992–1997), the D&E cores and the National Eye Institute provided support for a randomized clinical trial to compare a multicomponent (telephone, book, and award-winning video) intervention to standard medical care for increasing ophthalmic screening rates among African-Americans with diabetes (41–43).

Prevention and risk reduction remain as primary themes for current Albert Einstein College of Medicine D&E research (44–49). Models of Demonstration and Evaluation of Weight Loss Study (MODELS) received NHLBI support (1994–1999) and D&E and Biomedical Core support to develop an interactive computer system and the award-winning Complete Weight-Loss Workbook, which was published by the American Diabetes Association (50,51). A randomized controlled clinical trial evaluated the cost and clinical effectiveness of these intervention modalities in making weight control services more accessible in a managed care environment (52–54). This research work has extended to the development and evaluation of the WAVE—a quick method to address Weight, Activity, Variety, and Excess in primary care—with D&E core support and to the collaboration among medical schools in the Nutri-

tion Academic Award program (1998–2003) (55). Recent NEI funding (2000–2005) and D&E cores provided support for a randomized controlled clinical trial, Evaluating Alternate Retinopathy Screening Interventions (which was conducted in English and Spanish), to test the hypothesis that tailored telephone intervention increases the rate of dilated retinal examinations compared with standard print intervention. The clinical trial will also evaluate the relative costs and cost-effectiveness of the interventions. Another current collaborative project is Predictors of Medication Adherence: Barriers, Strategies and Perception of Risk. The project combines two areas of research interest: perception of risk for developing diabetes and medication adherence in the DPP. Risk perception survey data are collected in each of the four DPP centers that are also DRTCs. The project goals are to 1) gain insight into associations of risk perceptions to behavioral outcomes (including lifestyle) in the DPP, 2) to assist in the translation of DPP study findings, 3) to inform risk communities, and 4) to increase knowledge of preventive medication behaviors and predictors of adherence. The current D&E research effort builds on insights from earlier studies, such as the competing demands within health care systems and the patient-, provider-, and system-level barriers to achieving optimal diabetes outcomes in high-risk populations. Empirical evidence indicates that behaviorally oriented educational interventions can improve complications screening in a minority population and that technologies, such as telephones and computers, can optimize the use of resources (37,41,42,52,56). Thus, the D&E Cores have extended the sphere of research in the development, implementation, evaluation, and dissemination of study results, as well as collaborations with internal and external investigators who are examining diabetes-related health disparities.

Indiana University David Marrero, PhD, Professor of Medicine, Director, Prevention and Control Division. The authorizing legislation for DRTCs specifies that the D&E division 1) engages in research that translates the outcomes of biomedical and behavioral science research into clinical care and 2) develops and evaluates innovative methods and programs for translation activities. The Indiana University (IU)-DRTC

has responded to these mandates through the development and interaction of three core units: the Model Diabetes Unit (MDU), the Outreach Core, and the Educational Development and Evaluation Core (EDEC). Operationally, new clinical care and training models are developed and evaluated in MDU clinical settings with support by the EDEC. Validated models are then transferred to, and evaluated in, the community by the Outreach Core, again supported by EDEC.

Historically, the IU-DRTC D&E division focused primarily on determining the essential components of effective education for health care professionals. These efforts resulted in the development and validation of two pedagogical models for training health care professionals. The first focused on the application of multidisciplinary team care, with emphasis on the psychosocial correlates of treatment (57–65). The second emphasized altering the professional environment to facilitate the adoption of ideal standards of diabetes care (66,67). We applied these models to training programs that target patient populations that are either difficult to manage or at increased risk of acute and chronic complications of diabetes (e.g., adolescents, gravidas, and low-income minority patients) (68–76). Thus, if diabetes treatment is conceptualized as a continuum from primary prevention to tertiary management of end-stage disease, many of our prior activities focused on training health care professionals how to best apply strategies for optimal care of patients with established, complicated diabetes.

The IU-DRTC has also taken an active role in incorporating new technologies into clinical care. We were the first center to investigate the use of computers in analyzing self-obtained blood glucose data (77,78) and the first to conduct randomized control trials of point-of-care laboratory assessment (79,80) and telecommunication technology in diabetes management (81).

Over the past 5 years, the IU-DRTC has shifted its focus to primary and secondary prevention of diabetes and its complications. This focus is driven by two factors: 1) evidence that most patients with diabetes are not receiving optimal care (82–89) and 2) accumulating data suggesting that both type 1 and type 2 diabetes may be preventable and that intensive management of diabetes and new pharmacological interventions will sub-

stantially reduce the incidence and progression of complications. The IU-DRTC has developed projects that include 1) training health care professionals at all levels to promote prevention and slow the progression of disease, 2) developing care models for primary and secondary prevention that help practitioners make rational decisions concerning their use of clinical time and resources, and 3) transferring these models to the providers who care for high-risk, medically vulnerable patient populations (e.g., low-income, minority, elderly, and rural patients with diabetes) (90–93).

University of Michigan

Roland G. Hiss, MD, Coordinator, Prevention and Control Division, Michigan DRTC. The D&E Division of the Michigan DRTC (MDRTC) has pursued multiple themes beginning in 1977. One consistent theme throughout has been community-based diabetes care and translational efforts to improve this care (94–96). This involved comprehensive evaluation of 3,000 diabetic patients in 14 Michigan communities, determination of trend lines in diabetes care over 20 years, and development of a system that utilizes the patient as the agent for change in community diabetes care.

Minority health-related research and development programs (97–99) began in the late 1980s after Center Director Douglas A. Greene appointed a university-wide panel to advise us on health care issues in African-Americans. The MDRTC's research focusing on African-Americans with diabetes has yielded new knowledge useful in the development of culturally appropriate interventions targeting this population of patients. The *Living With Diabetes: Challenges in the African-American Community* patient education program developed by the MDRTC is being distributed nationally by the American Diabetes Association.

Development and validation of measurement and evaluation instruments (100–102) began in the early 1980s. The MDRTC has developed valid and reliable measures of diabetes-related knowledge, self-management behavior, attitudes, psychosocial self-efficacy, and psychosocial adaptation. In addition to use in our studies, these measures have been provided to >1,000 investigators worldwide. For the past 15 years, the MDRTC has developed, evaluated, and disseminated a collaborative approach to diabetes care

called “patient empowerment” (103–105). The empowerment approach has become one of the most widely adopted approaches to diabetes care in the U.S. and is attracting interest in countries as disparate as Mexico, the U.K., Germany, Sweden, Croatia, Australia, and Japan.

The MDRTC has developed and evaluated clinical programs for adolescents, type 1 patients using pump therapy, older adults, and patients with neuropathy (106–109) and has facilitated clinical research. As an example of the latter, considerable progress has been made defining the phenotype, natural history, genetics, and pathogenesis of maturity-onset diabetes of the young (110–112).

The MDRTC has developed professional and patient educational material in several formats (113–115). The center has offered professional symposia, undergraduate and graduate teaching for university students, and house officer training programs. Booklets, newsletters, and other educational materials have recently been revised and are available on the website.

Many of the products of the endeavors noted above are available through the MDRTC website (<http://www.med.umich.edu/mdrtc/>). These include 1) survey instruments (Diabetes Care Profile, Diabetes History, Diabetes Knowledge Test, Diabetes Attitude Scale, Diabetes Empowerment Scale, and the Michigan Neuropathy Screening Instrument) and 2) educational materials (*Diabetes Checklist* and *Facts and Questions* patient brochures and 22 information sheets on diabetes topics). *Life with Diabetes: A Series of Teaching Outlines*, *Teenagers with Type 1 Diabetes*, and *Type 2 Diabetes: A Curriculum for Patients and Health Professionals* were selected for publication by the American Diabetes Association.

Washington University

Edwin Fisher, PhD, Professor of Psychology, Medicine, and Pediatrics. The D&E Component of the DRTC at Washington University School of Medicine has long emphasized social and contextual influences on behavior in diabetes management as well as fundamental research on clinical diabetes and improvements in clinical diabetes care. Within the DRTC's MDU, a number of studies have examined enhanced clinical care, such as growth factors in the treatment of end-stage renal failure (116) or cognitive effects of intensive therapy in children with type 1 dia-

betes (117). Other studies address basic metabolic and endocrine functions, such as studies of leptin (118) or of metabolic factors in brain function (119). The vitality of this activity is reflected in 58 peer-reviewed papers reporting clinical diabetes research from the MDU between December 1999 and November 2000.

Reflecting the DRTC's emphasis on contextual influences, the MDU has, for over 20 years, supported research on family factors among children and adolescents with type 1 diabetes (120–124). Another area of research has examined the heightened prevalence of depression among those with diabetes (125), proceeding to investigate relations among symptoms of diabetes, depression, and metabolic control (126); more recently, the MDU has examined improved mood and metabolic control after treatment with both cognitive behavior therapy for depression (127) and fluoxetine (128).

Several projects have responded to the disproportionate burden of diabetes among minorities. Initial studies of family factors in pediatric diabetes and other childhood diseases that were developed primarily with white and mostly middle-class families were extended to African-American families with children with type 1 diabetes (129). Prevention of diabetes among African-American women has been the focus of dietary interventions implemented by peer educators (130). A current project extends previous research on organizational factors in improving diabetes patient education (131) to improve diabetes care in federally qualified health centers serving predominantly low-income African-Americans. Another current DRTC project extends the emphasis on peer educators to improve prevention of diabetes among adolescents living in American Indian tribal communities, and a third project examines peer educators in promoting exercise among older adults at risk for diabetes.

An exciting dimension of growth has been the collaboration with three other DRTCs that are also sites in the DPP (University of Chicago, Albert Einstein College of Medicine, and IU). Two collaborative projects address the influence in the DPP of acculturation among its African-American participants and the role of perception of risk. A third project has grown out of previous Washington University research on staff support in the DCCT. In this project, participants in the

DCCT intensive treatment group reported that staff reported substantially more nondirective support (cooperative without taking over, accepting feelings and choices) than directive support (directing what recipients do, think, and feel), which is somewhat counterintuitive, given the highly technical, demanding nature of the intensive treatment (132). The four collaborating DRTCs are now measuring support prospectively in the DPP. This will enable comparison of nondirective and directive support and their associations with adherence and quality of life in the DPP's lifestyle and medication arms.

Vanderbilt University. Over its history, the Vanderbilt University DRTC (VDRTC) has supported translational research in four areas: 1) health disparities in the African-American community, 2) research on adherence and barriers to adherence, 3) clinical intervention and outcomes research, and 4) research on teaching and problem solving for health professionals.

Disparities research. Beginning in the early 1990s, the VDRTC began to address the problem of type 2 diabetes in minorities. Research has ranged from studies of nutrition (133) to community-based interventions (134,135). Successes came about largely because of close collaborative relationships with African-American investigators from Meharry Medical College, Tennessee State University, Fisk University, the county health department, the county hospital, and an outstanding comprehensive health center. Every participating institution has played important roles in our mission to reduce and eventually eliminate Nashville's unconscionable racial health disparities in diabetes and cardiovascular disease.

Adherence, barriers to adherence, and measurement development. Examining the barriers to dietary adherence and ways to help patients overcome these barriers has been a long-standing VDRTC interest. Research in this area has historically been impeded by a lack of systematically developed outcomes measurement tools. The VDRTC's work attacked the problems several ways, including identifying barriers, developing taxonomies and measures of adherence problems, and mapping barriers to adherence in the community (136,137).

Clinical interventions and outcomes research. Since the DCCT ended, the challenges of attempting its widespread dissemination became clear: intensified therapy could not be provided in the vast majority of primary care settings (138); the expertise, personnel, and time were neither available in nor affordable for primary care offices; and market forces were working to limit patients' access to specialty care. One oft-cited alternative was "shared care." The concept, though intuitively appealing, was not well defined, its costs were not known, and its effects on patients and providers were only imagined. The VDRTC has evaluated two models of shared care. One, the Cumberland Pediatric Diabetes Network, involves general pediatricians (139). The second, the Diabetes Improvement Program (DIP), involves collaboration between Vanderbilt's diabetes specialists and physicians of general internal medicine (140,141).

Research on teaching and problem solving for health professionals. Another significant problem in translating the DCCT to practice was (and remains) the lack of readiness of the vast majority of health professionals to promote patient adherence through effective teaching and problem solving. The VDRTC established a track record of expertise in the development, evaluation, and dissemination of training for health professionals. Our Effective Patient Teaching and Problem Solving (EPT) course demonstrated reproducible, positive changes in professionals' skills (142). The VDRTC also developed and tested a training program called "Sugar Is Not a Poison" for dietitians, who learned to intensify diabetes medical nutrition management in the post-DCCT era (143). Finally, the VDRTC has joined other DRTCs in calling attention to the need for careful educational research in diabetes (144,145).

The VDRTC looks forward to continuing its history of contributing to new projects in the years to come, particularly in the areas of diabetes clinical care and the reduction of diabetes racial health disparities.

CONCLUSIONS

The wide array of approaches and the literally hundreds of publications by the DRTCs have expanded our knowledge of how to go from "bench to bedside." Moreover, the rigorous application of knowl-

edge from such diverse fields as the social sciences, behavioral medicine, education, epidemiology, statistics, economics, organizational theory, medical informatics, and health services research have led to significant advances in our ability to deliver high-quality diabetes care and improve the outcomes of patients. When the DCCT was completed, the DRTCs were asked to develop a strategic plan for its translation; the result, *Metabolic Control Matters*, became the template for the development of the implementation strategy by the National Institute of Diabetes and Digestive and Kidney Diseases and the CDC (138). Subsequently, these strategies have been incorporated into the National Diabetes Education Program, whose steering committee includes the DRTCs (146).

The future holds many challenges in the care of people with diabetes. The landmark DCCT was followed by the U.K. Prospective Diabetes Study, which demonstrated the efficacy of both glucose and blood pressure control in the reduction of vascular disease in people with diabetes (147,148). Similar data substantiate the beneficial role of lipid control and aspirin therapy in people with diabetes (149,150). We now must translate into clinical practice these and other studies, which, taken together, have shown us the way to dramatically reduce the microvascular, macrovascular, and neurological complications of diabetes. This will require a comprehensive care approach and a shift in the way many patients with diabetes are currently being treated. Finally, translating the results of the DPP presents us with an enormous clinical and public health challenge. Fortunately the 25 years of research by the DRTCs will help point the way.

APPENDIX

Contact information for the coordinators for the Prevention and Control Division of each DRTC and their corresponding DRTC grant numbers are listed below:

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