A Project to Reduce the Burden of Diabetes in the African-American Community: Project DIRECT

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Project DIRECT (Diabetes Interventions Reaching and Educating Communities Together) is the first comprehensive community diabetes demonstration project in the United States in an African-American community. This article describes its intervention components and evaluation design. The development and implementation of Project DIRECT has included the community since the project's beginning. Interventions are targeted in three areas: health promotion (improving diet and physical activity levels), outreach (improving diabetes awareness, detection of undiagnosed diabetes, and ensuring that persons with diabetes who are not receiving continuing diabetes care are integrated into the health-care system), and diabetes care (improving self-care, increasing access, and improving the quality of diabetes preventive care received within the health-care system). Evaluation will be internal (conducted by Project DIRECT staff to assess process outcomes in persons directly exposed to each specific intervention) and external (review of outcomes to assess the impact of the multi-intervention program at the level of the entire community). Because diabetes exacts a disproportionate toll among African Americans, the findings from this project should aid in developing strategies to lessen the burden of this disorder, particularly among minority populations. (*J Natl Med Assoc.* 1998;90:605-613.)

Key words: diabetes mellitus ◆ Project DIRECT ◆ community intervention ◆ health promotion ◆ quality of care

Over the past several decades, the prevalence of diabetes in the United States has increased.[1] African Americans, who have a higher prevalence of diabetes than US whites,[1] are also at greater risk than their white counterparts for diabetes-related complications of retinopathy,[1-3] kidney disease,[4-7] and leg amputation.[8] This disproportionate burden among African Americans is, however, not inevitable. Persons with diabetes can substantially reduce their risk of diabetic complications by improving glycemic control, obtaining adequate foot care, and receiving regular eye examinations, while treatment of cardiovascular disease risk factors can reduce heart disease.[9-13] There is also evidence that diet modification and increase in physical activity may prevent type 2 diabetes (the most common type of diabetes), for some people, although rigorous evidence for the effectiveness of these approaches is still forthcoming.[14,15]

In 1985, the Secretary of Health and Human Services' Task Force on Black and Minority Health

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identified diabetes as a major contributor to mortality among minorities in the United States. Two years later, the National Diabetes Advisory Board called for evaluation of the effectiveness of community-based demonstration projects designated to reduce morbidity and mortality associated with diabetes.

To respond to the excessive, unnecessary burden of diabetes among African Americans, the Centers for Disease Control and Prevention (CDC) has led the development, implementation, and evaluation of a multiyear community diabetes demonstration project called Project DIRECT (Diabetes Interventions Reaching and Educating Communities Together). Potentially, this project will be of great national interest and importance, and lessons learned from this pioneer endeavor may be applicable to other communities. This article describes the intervention components and evaluation design for Project DIRECT.

PROJECT DIRECT

Community interventions, which offer a way of promoting behavior change at many levels, can play an important role in preventing and controlling disease. When risk factors for a disease are both common and modifiable, and when the community environment influences risk factor modification, a community strategy should be considered. Such initiatives may have large payoffs; as suggested by Rose,[16] a small reduction in high-risk behaviors across the entire community can have a large impact at the population level.

Regardless of whether diabetes can be prevented, risk factors for developing type 2 diabetes, including poor diet and physical inactivity, are modifiable. A number of risk factors for developing diabetic complications such as poor self-care, inadequate access to care, and underuse of clinical screening for early diabetic complications also can be changed. Conceivably, a community intervention strategy could facilitate positive changes among persons at risk for diabetes, those who already have the disease, their health-care providers, and the health-care system in general.

Actual experience in the United States, however, has not been especially impressive, at least as demonstrated by the three largest community interventions to reduce cardiovascular disease risk factors and the largest one targeting smoking control.[17-20] All four studies found only modest improvements resulting from these initiatives, with the intervention communities performing only slightly better than the control communities. Although these trials were generally community-oriented, they did not target ethnic groups at high risk (for cardiovascular disease and smoking) and tended to display an inadequate understanding of the community structure and dynamics that influence change.[21] Because of the complexity of diabetes, effective community-based efforts require good understanding of the community structure and dynamics. Specific subpopulations, such as those at greatest risk for developing diabetes, diabetic complications, and diabetes-related disability, should be strategically targeted.

Project Development

In 1990, in collaboration with the Federal Agency for Health Care Policy and Research, the CDC began plans to develop, test, and evaluate a community-based diabetes intervention for African Americans. During the developmental process, a technical advisory committee to the CDC provided periodic review of project activities. In addition, 12 nationally recognized experts in diabetology, epidemiology, community health promotion, professional education, and minority affairs met regularly to review project progress and provide technical consultation.

Project DIRECT was designed to have pilot activities, baseline surveys, community interventions, and follow-up surveys. When completed, these components should provide information on effective survey methods, disease burden, risk factors, and successful interventions.

Community Selection

Project DIRECT is being conducted in the community located in the southeast section of Raleigh, North Carolina. This community was chosen for several reasons. First, the selected area is an African-American community. Second, key members of the community expressed interest in the project after being informed that it was being considered. Third, the North Carolina Department of Health and Human Services and the local health department, Wake County Human Services Department, strongly supported the project. Finally, local agencies had developed large networks of contacts in Wake County through other community projects and acquired an excellent understanding of the community's structure and function.

Pilot Study

A pilot study was conducted in 1993. A communi-

ty advisory board with broad representation of the community's civic, social, religious, professional, and medical leadership was formed for the pilot study. The board's role was to review the acceptability of survey instruments and methodology, and to advocate, promote, and encourage participation in the pilot survey within the community. The board selected the name Project DIRECT. During the pilot study, information was collected for designing community-based interventions and evaluating them. Pilot study results included assessment of expected community participation rates, acceptability of survey interviews and examinations, diabetes awareness, distribution of risk factors for diabetes, prevalence of diagnosed and undiagnosed diabetes and its complications, and current preventive health-care practices of persons with diabetes and of health-care providers.

The pilot study[22] successfully screened 1475 of 1884 sampled households. From the screened households, 1113 persons were selected for an interview. Of this group, 902 individuals (45% African American and 55% non-African American) participated for a response rate of 80%. Important findings included 52% of the African-American population in the community was physically inactive (only light or no physical activity during most weeks) and 51% was overweight (males >27.8 kg/m^2 and females >27.3 kg/m^2). The prevalence of diagnosed and undiagnosed diabetes was higher among African Americans than among those of other races in the target community (5.2% versus 2% and 5.7% versus 1.1%, respectively).

Compared with those of other races living in the community, African Americans were more likely to smoke and to have uncontrolled hypertension and were less likely to have a single health-care provider. In addition, among all persons with diabetes, the level of preventive care was low; within the last year only 42% had a diabetes eye examination and 50% had their feet examined by their health-care provider. The pilot study results identified areas for intervention, enhanced the development of intervention strategies, and helped refine methods for the baseline surveys.

Intervention Structure

The partnership of the southeast Raleigh community, the state Division of Community Health (Department of Health and Human Services), Wake County Human Services, and the CDC is supported by a community coalition. This coalition enjoys representation from key civic, social, and religious groups; medical, public health, and other professionals; and historically black colleges and universities. The Project DIRECT Executive Committee, which includes community and agency representatives, develops policies and guidelines, reviews and endorses action plans, reviews accomplishments through the year, and assists the project in identifying opportunities for visibility. The structure of the project is shown in Figure 1.

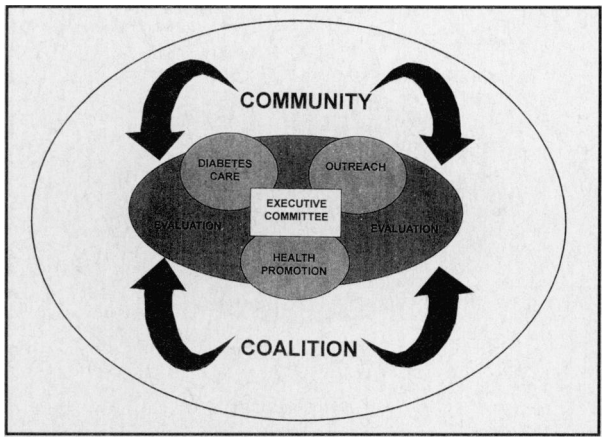

Figure 1.
Organizational structure of Project DIRECT.

Project DIRECT has three main intervention areas: 1) health promotion, 2) outreach, and 3) diabetes care (Figure 1). Each intervention area has a workgroup with its own coordinator; the workgroups include community members, health professionals, and representatives of local organizations. The workgroup coordinator plans and implements activities for each intervention area in consultation with the workgroup. The chairpersons of each workgroup are members of the Project DIRECT Executive Committee.

Health Promotion. Health Promotion interventions aim to reduce modifiable risk factors for developing diabetes in the general population (Figure 2). Observational studies,[23-25] one clinical trial,[14] and other reviews[15] have found modification of diet and physical activity effective in preventing the development of diabetes. Health promotion is focused on increasing participation in regular physical activity and decreasing fat intake. Among the initiatives in physical activity are walking programs held at community centers and parks and recreational facilities. Nutritional initiatives include the printing of articles and recipes on lower-fat cooking in local newspa-

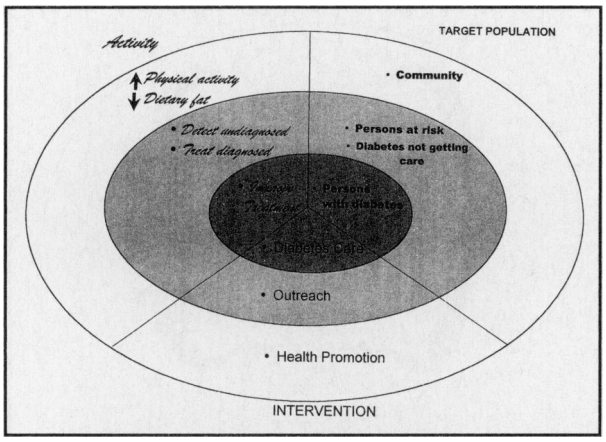

Figure 2.
Interventions, target populations, and activities for Project DIRECT.

pers, cooking demonstrations on television, and radio announcements that encourage low-fat cooking and eating. Work is planned with church kitchen committees to modify traditional recipes and cooking techniques.

Outreach. Through outreach, the project seeks to raise awareness about risk factors for diabetes; increase screening among those at risk, especially African Americans; and increase the percentage of those with diagnosed diabetes who are receiving continued diabetes care. Interventions to raise diabetes awareness include using the media (radio and newspapers), awareness activities in churches and public housing, and distributing educational materials in key community sites (businesses and health centers).

Screening for undiagnosed diabetes involves working with community partners including churches, community centers, public housing community groups, and civic groups, who provide sites and help with promotion. Persons found to have elevated blood glucose concentrations are scheduled for further testing and are tracked by project staff to determine whether they complete follow-up. Those who are newly diagnosed with diabetes are referred for medical care and then tracked to determine whether they make the contact suggested. Project DIRECT also refers and tracks persons previously diagnosed with diabetes who have stopped receiving care.

The effectiveness in detecting undiagnosed diabetes through screening is not known; this issue has not yet been studied directly. However, several influential organizations including the American Diabetes Association, the British Diabetic Association, and the World Health Organization have recommended screening for those at risk for diabetes.[26-28] One argument in favor of screening comes from studies suggesting that glucose concentrations commonly found in undiagnosed cases, if improved, could prevent or delay development of diabetic complications.[10, 29-31]

Diabetes Care. The goals of the diabetes care component are to improve self-care practices, increase access, and improve quality. Clearly, good preventive care prevents or delays the development of both diabetic and cardiovascular disease complications.[9-13]

Diabetes care activities include various self-management workshops; sessions address diabetes-related nutrition, physical activity, blood sugar and medication management, and filing for insurance. Attendees are strongly encourage to improve self-care practices through education, training, and personal innovation.

Project DIRECT is working with primary care providers to improve the quality of diabetes care; current practices are assessed through medical record reviews, and results are compared with each provider's desired practice goals. Providers are being assisted through implementation manuals, resource materials, and individualized practice plans. Practice goals may include providing more regular eye and foot examinations, and detecting and treating cardiovascular disease risk factors (eg, hypertension, hyperlipidemia, and smoking).

Community Evaluation: Internal and External

A comprehensive evaluation of Project DIRECT is critical to determine what has been accomplished and, if appropriate, to implement such a program in other communities, if it has been found to be successful. Thus, the evaluation plan will have both internal and external levels. An evaluation team, working closely with the health promotion, outreach, and diabetes care workgroups, will design and conduct internal evaluations of each intervention. This team will include health promotion, outreach, and diabetes care workgroup members; community and agency representatives; and scientific and technical consultants. The external evaluation will be a population-based assessment to determine the impact of Project DIRECT in the entire community at the population level (regardless of direct exposure to the three intervention areas). This evaluation will be conducted by CDC staff and supporting agencies not involved with developing and evaluating Project DIRECT intervention activities.

Internal Evaluation. The internal evaluation will

primarily consist of assessing process outcomes (eg, frequency of participation in programs). Intervention-specific evaluations for health promotion physical activities will include participation rates and estimates of media coverage for promotion of those activities. The media coverage of messages on low-fat cooking and participation by churches in teaching low-fat meal planning also will be examined.

For outreach activities, relevant media coverage will be examined; for outreach screening efforts, evaluation will include the proportion of the population at risk for diabetes who are actually screened. Evaluations also will track the proportion who complete their referral to follow-up testing, and, for newly diagnosed persons, to professional care.

For diabetes care, follow-up medical record reviews will examine changes in practice from the baseline assessment. Process measures to be evaluated will include the use of flow sheets for diabetes care in medical records. Outcomes will include the percentage of people with diabetes who receive an annual dilated eye examination, foot inspections, and measurements of hemoglobin A1c (an indicator of long-term glycemic control). For diabetes care self-management classes, knowledge and skills will be assessed and participant feedback on the sessions will be reviewed. Internal evaluation in each intervention area will provide valuable feedback to each of the intervention workgroups and will be used in modifying current interventions and planning future activities.

External Evaluation. The population-based external evaluation will assess the effect of the total intervention package in changing community-level health behaviors, diabetes awareness, screening of persons at risk for diabetes, and care received by persons with diabetes. Because change observed between the baseline and follow-up surveys could be the result of the interventions or of secular or societal trends, the same baseline and follow-up assessments are planned in a single comparison community that did not receive the interventions.

The comprehensive external evaluation will include surveys, focus groups, and interviews. Cross-sectional surveys will be taken of individuals sampled from the intervention and comparison communities to assess primary and secondary outcomes by taking a baseline measurement and one at the project's end (planned to be 5 years after the start of the interventions; an intermediate assessment is being considered). The focus groups will be designed to describe qualitatively the community-based networks important for diabetes prevention and control. Individual interviews will be conducted with key community members to assess qualitative changes in community support of diabetes control efforts. The external evaluation is being conducted by the CDC in conjunction with agencies not involved with Project DIRECT.

Outcomes for the external evaluation of the health promotion, outreach, and diabetes care areas are presented in Table 1. Baseline prevalence for the specific areas of interest was obtained from the Project DIRECT pilot study or, in some cases, from national surveys. These rates will be refined when data from the baseline survey are available. For some secondary outcomes areas, the target population will be a subset of the total population (eg, smokers with diabetes). Target values were selected to show meaningful improvement in the population during the 5-year intervention period; they are considered realistic but still demanding enough to be challenging and also clinically relevant.

For scientific sampling purposes, a well-defined area in Raleigh that includes the targeted community and a similar comparison area in another city in North Carolina were identified for the external evaluation. The designated area in the intervention community consists of a group of seven census tracts in southeast Raleigh; the comparison community selected is in Greensboro, a city of similar size approximately 100 miles from Raleigh. Both of these delimited areas have populations of about 17,000 adults (adults $\geq$18 years who constitute the population were considered for this evaluation). Both areas have similar socioeconomic and health-care resource profiles (Table 2).

In each community, approximately 800 African-American adults are expected to have diagnosed diabetes. Choosing a sample size involved several considerations: 1) the estimated prevalence of diabetes in the communities (5% from the Project DIRECT pilot study), 2) 80% power for the primary outcomes and a 5% probability of a type 1 error for primary outcomes, and 3) performing both pre- and postintervention measurements in both intervention and comparison communities. In each community, we expect to contact approximately 4400 households and interview 900 persons without diabetes and 300 persons who have diagnosed diabetes.

Both intervention and comparison communities will be studied through population-based household

Table 1. Summary of Outcomes for the Project DIRECT External Evaluation

Category	Target Population	Baseline Level (%)	Target Level (%)
Health Promotion			
Primary			
Improving diet (% with high-fat diet)	Total	50	40
Engaging in exercise (% who exercise vigorously)	Total	40	50
Secondary			
Weight reduction (% of those overweight who are attempting to lose weight)	Males	57	67
	Females	73	83
Outreach			
Primary			
Knowledge (% aware of diabetes risk factors)	Total	30	40
Screening (% at risk persons screened for diabetes)	At risk	36	46
Care (% with diabetes receiving appropriate care)	Diabetic	64	80
Diabetes Care			
Primary			
Eye (% with annual diabetic eye examination)	Diabetic	42	60
Foot (% receiving biannual foot examination)	Diabetic	50	75
Education (% receiving diabetes education)	Diabetic	42	57
Secondary			
Smoking cessation (% smokers counseled to quit)	Diabetic smokers	42	55
Hypertension (% with hypertension who are treated)	Diabetics with hypertension	76	85
Cholesterol (% with high cholesterol)	Diabetics with hyperlipidemia	29	19

cross-sectional surveys of the general population and of persons with diabetes. The baseline and follow-up surveys will have independent samples to assess the effects of the project on the community as a whole, not just those community members surveyed at baseline.

A household survey will collect information from all participants to evaluate the outcomes and will include questions on demographic, socioeconomic, and health status variables; exercise; diet; weight control; tobacco use; diabetes risk factors; and diabetes screening history. Participants with diabetes will be asked additional questions about the quality of care they receive for diabetes, their self-care practices, exposure to diabetes education, and access to health care. Finally, persons with diabetes will be asked to provide a blood specimen to assess their glycemic control, kidney function, and lipid concentrations.

A provider survey will collect information from primary care physicians (general practitioners, internists, and family practitioners) on their diabetes practices, referral patterns, and level of care provided, particularly with regard to glycemic control, cardiovascular disease risk factors, and eye and foot care. Because there are fewer than 100 primary care physicians in each community, all of these physicians will be surveyed.

Focus group information will be used to describe qualitatively the communities' social networks: 1) primary social networks for community members (eg, churches, work sites, neighborhood associations, and social and civic organizations) will be identified, 2) the support that social networks provide for good diabetes prevention and control will be described, and 3) services, orientations, knowledge, and behaviors of community organizations and institutions that increase social support for diabetes will be identified. Focus groups also may provide valuable information that will help interpret community survey results. Each community will

Table 2. Characteristics of Intervention and Comparison Communities

Characteristic	Community	
	Intervention No. (%)	Comparison No. (%)
Population		
Total	24,851 (100)	25,800 (100)
African Americans	23,360 (94)	24,768 (96)
African American ≥18 years	14,950 (64)	16,099 (65)
Total households	9393 (100)	9695 (100)
African-American households	8847 (94)	9307 (96)
Estimated prevalence of diabetes		
Total	(4.8)	(4.9)
African American	(5.0)	(5.0)
Non-African American	(2.5)	(2.5)
Age ≥65 years	(12)	(12)
African American	(18)	(18)
Non-African American	(12)	(12)
Health-care resources		
Acute care hospitals	3	4
Hospital beds	1047	917
Primary care physicians	115	102
Sociodemographic		
Telephone in home	87	88
Persons with diabetes living below poverty level	33	33
African American	33	33
Non-African American	12	12

have six focus group meetings (approximately 10 attendees at each meeting); four will have persons with diabetes and two will be for persons without diabetes.

The final component of the external evaluation involves individual interviews. These sessions will be conducted with community members perceived to have potential roles in community change, such as grocery store owners, exercise club staff, and community leaders as well as health-care providers. The interviews should provide qualitative information about community changes in behavior patterns and perceptions as well as social networks and behavior and expressed attitudes of community institutions.

DISCUSSION

In the United States, diabetes is the seventh leading cause of death, the leading cause of kidney failure and lower extremity amputations, as well as blindness in working aged adults; it is also a major cause of heart disease.[8,32,33] In economic terms, the burden of diabetes is staggering; it was estimated to account for $92 billion in direct (ie, health-care expenditures) and indirect (ie, short- and long-term disability and premature death) costs in 1992.[34] The economic impact on individuals with diabetes, including out-of-pocket expense, and to the community and workplace, is also considerable.[8]

Healthy People 2000 stresses the great harm by diabetes on African Americans and other minority groups and addresses the disparities between various populations in the disease's impact.[35] Initiatives such as Project DIRECT that specifically target African-American communities reflect the CDC's commitment to carry out the messages of Healthy People 2000.

Although some community interventions for chronic diseases have had limited impact, four compelling reasons argue that this approach is appropriate for diabetes. First, sound science-based research has shown that diabetic complications and disability in persons with diabetes can be delayed or prevented. There is also an emerging science base that sup-

ports consideration of primary prevention strategies for diabetes.

Second, diabetes is a disorder that requires integrated approaches at multiple levels. The desired broad-spectrum approach requires, in addition to a variety of preventive initiatives, that persons with diabetes receive specific elements of medical care, have access to healthy foods, and be able to participate in physical activity. To be effective, such a comprehensive approach requires involvement of the health-care system, individuals, families, the workplace, and the community.

Third, Project DIRECT is the first community project with a comprehensive approach to reducing the burden of diabetes that includes interventions at all three levels of prevention: primary (to reduce risk factors for diabetes), secondary (to improve identification of individuals with a disease and improve the level of care to prevent development of diabetic complications), and tertiary (to improve the quality of care to prevent disability). Previous community-based approaches have rarely included tertiary prevention.

A final reason for pursuing an initiative such as Project DIRECT is to assess a community diabetes intervention that intimately involves the community in its development and implementation. Understanding the community structure and having the community involved in the design and implementation of such interventions may be critical to the success of such initiatives. Poor understanding of the community structure and how it changes as well as not targeting specific subpopulations may have contributed to the poor outcomes of other community interventions.[21] Project DIRECT not only characterized the community during the pilot study,[22] but also involved its members in project development from the formative stages.

Outcomes that assess the processes of clinical care delivery and participation in preventive health behaviors were selected for Project DIRECT's external evaluation. However, preventing specific clinical outcomes, such as the development of diabetes or its complications (eg, eye or kidney disease) are the ultimate goals of this type of community intervention. Process outcomes selected for this evaluation should represent real changes in the community that can be detected during the time frame of the project and ideally have a substantial effect on the long-term clinical outcomes.

Evaluation through cross-sectional population-based surveys of persons with and without diabetes, conducted in both the intervention and comparison communities, will allow for secular changes and should provide a broad picture of differences at the community level. Cohort follow-up evaluations would be a powerful method to assess changes in preventive care and to assess clinical outcomes, but this design would not allow assessment of change in the entire community. In addition, because the project will take place over several years, a cohort established at the time of the baseline survey might suffer from considerable attrition and require extensive tracing by the follow-up survey.

The challenges posed by Project DIRECT to the CDC and cooperating groups and organizations in North Carolina notwithstanding, the public health approach embodied in this initiative holds great promise. A community- and population-based approach, as represented by Project DIRECT, may provide an environment where behavior change may occur more easily and ultimately benefit a large portion of the population. In addition, Project DIRECT may have an effect beyond diabetes and its usual complications: several behaviors, such as improved levels of physical activity and healthier eating habits, may positively affect the course of many chronic diseases.

CONCLUSION

Project DIRECT is an innovative, unique approach to addressing diabetes in the African-American community. The health promotion, outreach, and diabetes care interventions developed and implemented with community participation will provide an excellent opportunity to evaluate this approach. Because diabetes exacts a disproportionate toll among African Americans, findings from this project should aid in developing strategies to lessen the burden of this disorder, particularly among minority populations.

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