# Screening for Diabetes in an African-American Community: The Project DIRECT Experience

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Aim: To report the results of a community-based screening program associated with Project DIRECT, a multiyear diabetes mellitus prevention and control project targeting African-American residents of southeast Raleigh, NC.

Methods: Between December 1996 and June 1999, 183 screening events took place in community settings. Screening was by capillary glucose concentration. Participants with a positive screen were referred for confirmatory testing and physician follow-up.

Main Results: Risk factors for diabetes were prevalent, including ethnic minority race (88.2%), obesity (45.6%), and family history of diabetes (41.7%). In all, 197 persons had an elevated screening result; the prevalence of diabetes in the screened population that underwent follow-up testing was 1.7%. Despite persistent tracking efforts, 28% of the persons with a high screening test received no final diagnosis.

Conclusions: In this community-based screening program targeted to high-risk African Americans, risk factors for diabetes were common, but new cases of undiagnosed diabetes among participants were uncommon. Intensive follow-up for persons with high screening values is necessary but difficult to achieve. Our results support national recommendations against community-based screening; opportunistic screening for diabetes in clinical settings is likely a more effective use of resources.

#### Key words: diabetes mellitus Screening African Americans

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#### INTRODUCTION

Undiagnosed diabetes mellitus contributes significantly to the overall morbidity and mortality caused by this disease.<sup>1</sup> In the United States, the prevalence of undiagnosed diabetes is 2.7%, and this rate is greater in ethnic minority populations than among whites.<sup>2</sup> The best approach for detection of undiagnosed diabetes remains open to debate. Currently, the American Diabetes Association (ADA), the U.S. Preventive Services Task Force, and others recommend opportunistic screening in clinical settings,<sup>3-5</sup> although organizations differ in their opinions on which patients to screen. The ADA and others oppose community-based screening, such as in churches or at health fairs.<sup>3,5</sup> Screening for undiagnosed diabetes remains popular, however, among community groups and in public health programs,<sup>6-9</sup> and some suggest that community-based screening may be appropriate in high-risk populations.9

One of the challenges in determining how best to detect undiagnosed diabetes is that communitybased screening programs are rarely evaluated, and there is little data on their limitations. These limitations include the difficulty and cost in tracking persons with high screening values to ensure that they receive confirmatory testing as well as proper care once diabetes has been identified. In addition, the debate on the value of community-based screening has grown more complex with the recent data on successful diabetes prevention in patients with prediabetes, since community-based screening is potentially a mechanism to identify patients with this condition as well.<sup>10,11</sup>

We report here the results of a community-based screening initiative conducted from December 1996 to June 1999 in association with Project DIRECT, the first large-scale diabetes control project developed within an African-American community.<sup>12,13</sup> Pilot data for this ongoing project, which targets certain census tracts in southeast Raleigh, NC, were collected in a random household survey in 1993. A significant burden of diabetes was confirmed: the

Table 1. Sociodemographic and Clinical Characteristics of Persons Eligible for Screening (N=2,699)			
	N	n (%)	
Age, Years 20–44 45–64 65+	2,699	1,492 (55.3) 841 (31.2) 366 (13.6)	
Male	2,684	924 (34.4)	
Race African-American White Other	2,344	2,022 (86.3) 277 (11.8) 45 (1.9)	
Education Any graduate/ professional education College degree	2,677 on	282 (10.5) 605 (22.6)	
Some college education Technical or vocational training Grade 12 or GED Less than high school diploma		625 (23.4) 271 (10.1) 595 (22.2) 299 (11.2)	
Residence in southeast Raleigh	2,698	1,200 (44.5)	
Insurance* Through employer Medicare Medicaid IHS/Champus/ military/other	2,673	1,540 (57.6) 276 (10.3) 137 (5.1) 387 (14.5)	
None Years Since Last Visit to Physician for a Routine Checkup <1 year 1–5 years >5 years Don't know	2,687	333 (12.5) 1,942 (72.3) 579 (21.6) 105 (3.9) 61 (2.3)	
Needed to see a physician in last 12 m but could not becau of cost, % yes	onths se 2,690	383 (14.2)	
Usual Source of Care Private physician Health department Hospital clinic Emergency room Urgent care center/c Nowhere	2,308 other	1,573 (68.2) 180 (7.8) 139 (6.0) 137 (5.9) 219 (9.5) 60 (2.6)	
* Insurance used to pay for most of medical care; GED: General Education Development; IHS: Indian Health Service			

overall prevalence of diabetes in African Americans in the target area was 10.8%, and the prevalence of undiagnosed diabetes was 5.5%.<sup>13</sup>

The two-and-a-half-year screening program, which was part of a multifaceted outreach intervention, represents the largest diabetes screening effort in an African-American community reported in the literature. In addition to identifying new cases of diabetes, the program goals were to ensure medical care for those with newly diagnosed diabetes as well as to return to medical care those persons with known diabetes who presented for screening and did not have a healthcare provider.

## **METHODS**

## Intervention

The screening intervention and protocol were designed and overseen by the Outreach Workgroup, with representation from the community as well as public health partners. The target population was the approximately 25,000 adult African Americans living in seven census tracts in southeast Raleigh.<sup>14</sup> The goals of the screening intervention were to: 1) detect undiagnosed diabetes, especially among African Americans in the target community; 2) enter those detected into the healthcare system; 3) see that those previously diagnosed were in the healthcare system; and 4) use encounters to provide information about diabetes, DIRECT activities, and ways to reduce risk factors for diabetes.

The outreach and screening coordinators identified "screening partners"—local organizations that facilitated the conduct of screening events at their sites. Partners were identified through contacts from the Outreach Workgroup, volunteers, and churches. Methods to recruit participants built upon the outreach strategies developed for the pilot phase of Project DIRECT and were specifically designed to eliminate barriers to participation and to enhance trust between the community and the researchers.<sup>15</sup> These included advocates, who were local residents trained to publicize the events within the public housing communities and other southeast Raleigh neighborhoods; media campaigns, including radio, billboards, and flyers; and "ambassadors," volunteers from local service organizations who were trained to speak at meetings and other gatherings to publicize the screening events.

Events were held in churches, community centers, senior centers, public housing developments, local businesses, and community organization headquarters. In addition, screening was conducted in conjunction with other events, such as health fairs. Those interested in screening were checked for eligibility (see below) by a coordinator. If eligible, they completed informed consent as well as registration forms. The registration forms asked about history of diabetes, including gestational diabetes, or history of taking diabetes medications; sociodemographic characteristics; medical history; and access to care, including having health insurance and regular medical care. Those eligible underwent capillary glucose screening, and a screening nurse interpreted the results and provided education. Persons with a normal result but who had indicated risk factors for diabetes on their registration form were provided with counseling about community services, including DIRECT intervention activities, to address those risk factors.

#### **Participants**

The eligibility criteria for screening were as follows: age  $\geq 20$  years, not pregnant or within three months of being pregnant, not breastfeeding or within six weeks of breastfeeding, no hospitalizations in the last six months, no previous diagnosis of diabetes (excluding gestational or steroid-induced diabetes), and no previous use of diabetes medications. History of diabetes was self-reported; participants were asked if they had ever been told by doctor or other health professional that they had "diabetes (high blood sugar)," and asked if they had "ever taken medicine for diabetes, such as insulin or diabetes pills." In 1998, a new criterion of no food intake in the last 1.5 hours was introduced because many people were presenting for screening who had recently eaten, but this criterion was not consistently enforced. Our analyses, therefore, include some persons with recent food intake. Persons with a history of diabetes who were without a current source of medical care were eligible for tracking and follow-up.

## Definition of a Positive Screen and Confirmatory Testing

The criteria for a positive screen, adapted from published studies,<sup>16</sup> were the following: capillary glucose (CG)  $\geq$ 110 mg/dl and no food intake in the last three hours; CG  $\geq$ 115 mg/dl and no intake in the last 1.5–3 hours; or CG  $\geq$ 125 mg/dl and no intake in the last 1.5 hours. Persons with a CG  $\geq$ 250 mg/dl and with symptoms of hyperglycemia were referred to a local emergency room.

A lead screening nurse reviewed all the screening forms to identify persons requiring follow-up and tracked all persons with positive screens. Before 1998, the nurse referred persons with a high screen for follow-up oral glucose tolerance testing (OGTT) at the Wake County laboratory in Raleigh. Persons with a fasting glucose  $\geq 140$  mg/dl or two-hour glucose of  $\geq 200$  mg/dl were categorized as having a diagnosis of diabetes. The nurse referred these patients to their physician or to a new physician if they were without regular care. Beginning in 1998, however, persons with a high screen were referred to their own or a new physician for further testing and diagnosis. As part of the informed consent obtained from participants, Project DIRECT was able to contact participants' providers directly. Using a documented protocol, the screening nurse made followup phone calls and letters to patients and physicians to ascertain whether a diagnosis of diabetes had been confirmed. In most cases, the patient's selfreport rather than a physician's report was obtained to record an outcome.

In numerous instances, the participants were reluctant to return for OGTT or unable or unwilling to see a physician after being diagnosed by OGTT. In all cases, the screening nurse attempted to identify and address barriers to further evaluation. The protocol specified the number of attempts the nurse should make to contact participants before they were terminated from the tracking system. For a person with a high screen, the protocol required three phone calls, one letter, and one certified letter; for someone with a diagnosis of diabetes by OGTT, it required one letter with the test results, three follow-up phone calls, and one certified letter.

#### Data Analysis

Data were obtained from registration forms as well as tracking forms completed by the screening nurse. Data were analyzed using STATA (Version 6.0; Col-



lege Station, TX) statistical software. Distributions of sociodemographic and clinical variables are reported. Characteristics of persons with incomplete follow-up were compared with those having successful follow-up using t-tests and Chi-squared analyses.

#### RESULTS

### **Program Implementation**

During the program's 30 months, 183 separate community screening events occurred. The sites included churches (34%), businesses (22%), public housing or community centers (14%), social or human service organizations (14%), schools (11%), and other sites (6%). Twenty percent of screening was conducted as a part of another event, such as a health fair, concert, or celebration; 80% took place at stand-alone events. Participants heard about the screening from church (20%); an outreach worker (18%); through a brochure, flyer, or poster (17%); from a family or friend (12%); from the radio (4%); from a newspaper advertisement or article (3%); or from television (3%).

Of the 3,356 persons who registered for screening, 90 had missing registration forms and 105 were identified as repeated screens. Results from only the first screen were included. Of the remaining 3,161, 105 had a previous diagnosis of diabetes and were

Table 2. Risk Factors for Diabetes among Persons Eligible for Screening (N=2,699)			
	N	n (%)	
Age ≥45 years	2,699	1,207 (44.7)	
Nonwhite race	2,344	2,067 (88.2)	
Obese (BMI ≥30)	2,614	1,191 (45.6)	
Physically inactive (physical activity <3–4 times/week)	2,688	1,486 (55.3)	
Gestational diabetes or newborn >9 lbs, among women	1,760	216 (12.3)	
Family history of diabetes (sibling or parent)	2,699	1,125 (41.7)	
Hypertension*	2690	866 (32.2)	
Hypercholesterolemia**	2,682	725 (27.0)	
* Self-reported "ever" diagnosis by a doctor or health professional of high blood pressure or hypertension; ** Self-reported "ever" diagnosis by a doctor or health professional of high blood cholesterol; BMI: body mass index			

ineligible for screening, 2,699 were eligible for screening, and an additional 357 were otherwise eligible and screened but not included in analyses because information on age, an actual eligibility criterion, was missing.

# **Participant Characteristics**

The overall sociodemographic characteristics of all persons who were eligible for the screening (N=2,699) are represented in Table 1. Participants were predominantly young or middle-aged; only 14% were age 65 or older. Most participants were female, 86% were African-American, and 33% had a high-school education or less. Less than half were from the target area of southeast Raleigh. Thirteen percent were uninsured, and 14% reported needing physician care in the last year but not being able to afford a visit. Just over two-thirds saw a private physician for their medical care.

The prevalences of risk factors for diabetes among the 2,699 eligible for screening are reported in Table 2. The prevalences of most risk factors for diabetes were high, including ethnic minority race (by self-report), obesity, physical inactivity, and family history of diabetes. Over half the participants, however, were below age 45 (the current ADA recommended age to begin diabetes screening).

#### **Results of Screening**

In Figure 1, we report the results of the 2,699 persons with no previous diagnosis of diabetes who received screening. One-hundred-ninety-seven (7%) had a high screening value and were referred to the Wake County laboratory (through 1997) or to a physician (1998–1999) for diagnosis. One-hundred-fortyone (72% of 197) completed the referral, and 56 (28%) did not. Forty-five of the 141 who completed the referral were confirmed to have diabetes (prevalence of 45/2,699=1.7%). Thirty-seven of these 45 (82%) were also seen by a physician (one goal of the program was to ensure care for the newly diagnosed). Ninety-six were confirmed not to have diabetes. The positive predictive value of the screening criteria was 32%, based on those who completed the referral. The positive predictive values for the criteria among those who were referred for OGTT or for physician evaluation were similar (data not shown).

Only 19 of 105 persons who reported a previous diagnosis of diabetes were without current medical care. Of these, six were successfully referred to a new provider, and we have no recorded outcome for the other 13.

## **Evaluation of Tracking Process**

Persistent follow-up was required for tracking and ensuring appropriate care of those with a high screen or a new diagnosis. A total of 787 phone calls to patients were made (range per person, 0-15; median, 4). Seventy-four letters were sent (range, 0-2; median, 0), and 57 certified letters used (range, 0-2; median, 0). In addition, the nurse made many calls to the county laboratory to arrange testing, to physician offices to schedule appointments or obtain results, and to local agencies to assist patients with transportation.

Despite these efforts, 64 persons (32% of 197 with a high screening test) had either no final diagnosis (n=56) or no physician visit after a diagnosis of diabetes from a positive OGTT (n=8). Of this group, nine (14%) terminated the process themselves. DIRECT terminated the process after the appropriate number of calls and certified letters (i.e., according to protocol) for 33 (52%), and with fewer than the number of calls or letters specified by protocol for 22 (34%). Of 13 persons with a previous diagnosis of diabetes and no medical care who were not successfully reinstated to medical care, tracking was terminated by DIRECT according to protocol for eight.

We investigated the characteristics of these persons who had no final diagnosis or no physician visit after a diagnosis of diabetes from a positive OGTT, compared with those persons who were successfully tracked, to see whether sociodemographic or clinical characteristics were associated with difficulties in the follow-up and tracking process. Of the demographic and risk factor characteristics reported in Tables 1 and 2, only two were associated with lack of a recorded outcome: education of high school or less (p=0.01) and white race (p=0.05) (the latter being of only borderline statistical significance). There were no differences in follow-up rates by the site where the person was screened.

#### DISCUSSION

The Project DIRECT screening intervention was successful in attracting persons with a high prevalence of most risk factors for diabetes, but the yield of new cases was low. The prevalence of undiagnosed diabetes, 1.7%, is well below the comparable prevalence of 5.5% found in the pilot survey, a random household survey, of this community. Several characteristics of the screened population may account for this. First, over half the persons screened were less than 45 years old, although 45 is the current recommended age to begin diabetes screening.<sup>3</sup> Second, as judged by their access to care and education level, the participants were probably above the average socioeconomic status for the target area (per the 1990 census, 35% of residents in the seven census tracts had less than a high school degree<sup>14</sup> vs. 11% of those who presented for the screening program). The fact that less than half of the participants were from the target area may explain the

findings of higher-than-expected socioeconomic status and highlights the difficulty in reaching the targeted, underserved population. Churches in southeast Raleigh were active partners in this intervention, yet their congregations often extended beyond the target area. Finally, local providers were also involved in Project DIRECT interventions and may have already diagnosed some of the cases that would otherwise have been detected through screening.

Yields in other screening programs reported from the United States and other westernized nations in the literature are similar.9,17-23 An exception is a recent study that recruited participants from physician practices as well as from the community in five cities in three separate states;<sup>24</sup> this study had over 88% ethnic minority participants, including 58% Hispanics, and found a prevalence of undiagnosed diabetes of 10.7%. In Project DIRECT, however, a unique example of a community-based screening initiative targeted to an African-American population, we would expect the yield to be higher than 1.7%. Furthermore, towards the end of the program, when preliminary results suggested a low yield, the screening coordinator made special efforts to schedule screenings in more underserved parts of the community, for example, homeless shelters. Our results suggest that even when targeted towards perceived high-risk and underserved communities, community-based screening will have a lower-than-expected yield and will require intensive follow-up. Our results support the recommendations of the American Diabetes Association against community-based screening.<sup>3</sup> They stimulate further research questions, however, into why persons at high risk for diabetes do not participate or decline follow-up. These questions could be answered through qualitative studies and should be addressed if community-based screening continues in communities in the United States.

Our data on the characteristics of persons screened as well as our evaluation of the follow-up process should provide insight for other communitybased screening efforts. Because community screenings remain popular, both with the general public and with many public health programs, public health practitioners need better data on their feasibility and the amount of follow-up needed to track persons with a positive screen. As noted by others, the effectiveness of a screening program relies upon the change in clinical management that occurs after a person is diagnosed as well as the prevalence of the condition or the characteristics of a screening test.5,25 The percentage of persons with a high screen for whom we do not have a final diagnosis (28%) despite persistent follow-up attests to the challenges of a community-based screening initiative. Also, we did not explicitly measure costs of the program; future screening efforts should include an evaluation

of cost-effectiveness of community-based screening.

Several aspects of the program limit our findings. The most important is the change in criteria for diagnosis that took place in 1998 and the potential for misclassification. Our definition of diabetes includes both persons diagnosed by OGTT as well as those patients who self-reported a physician diagnosis. We have no data on tests used to diagnose or exclude a diagnosis of diabetes in patients referred to physicians. Also, we have evidence that some of the inclusion and exclusion criteria were not followed uniformly-specifically the exclusion criteria introduced in 1998 of no food intake within 1.5 hours. Finally, incomplete registration forms led to a significant amount of missing data in the analyses. This issue was a known challenge during the intervention and was addressed by offering participants help in completing the forms and by having the coordinators review all forms for completeness prior to screening.

This screening program took place as a part of the overall outreach intervention and grew directly from the pilot survey, which involved a household survey and diabetes screening. We are not able to analyze with this data the extent to which the screening intervention contributed to an important outcome of outreach, increased education about diabetes, its symptoms, and the importance of screening. An additional evaluation of Project DIRECT, a household survey to be completed in the next few years, will, however, contribute important information on the efficacy of the screening interventions at the population level. Community-level measures of diabetes knowledge and the proportions of persons who report ever being screened for diabetes (and site of that screening) will be compared with the baseline measures of 1997. We will thus have indirect measures of this additional effect of the screening intervention.

#### CONCLUSION

In this community-based screening program targeted to high-risk African Americans, risk factors for diabetes were common, but new cases of undiagnosed diabetes among participants were uncommon. In addition, persistent follow-up was required and a significant proportion of participants had incomplete follow-up. Our findings support the recommendations of the American Diabetes Association against community-based screening.<sup>3</sup> Communitybased diabetes control efforts are likely better focused in other areas, such as increasing opportunistic screening during routine clinical care, improving quality of care, or increasing access to self-management education.<sup>11,26,27</sup>

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