Nurse-Community Health Worker Team Improves Diabetes Care in American Samoa

Results of a randomized controlled trial

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OBJECTIVE—To evaluate the effectiveness of a culturally adapted, primary care-based nursecommunity health worker (CHW) team intervention to support diabetes self-management on diabetes control and other biologic measures.

RESEARCH DESIGN AND METHODS—Two hundred sixty-eight Samoan participants with type 2 diabetes were recruited from a community health center in American Samoa and were randomly assigned by village clusters to the nurse-CHW team intervention or to a wait-list control group that received usual care.

RESULTS—Participants had a mean age of 55 years, 62% were female, mean years of education were 12.5 years, 41% were employed, and mean HbA1c was 9.8% at baseline. At 12 months, mean HbA1c was significantly lower among CHW participants, compared with usual care, after adjusting for confounders (b = -0.53; SE = 0.21; P = 0.03). The odds of making a clinically significant improvement in HbA_{1c} of at least 0.5% in the CHW group was twice the odds in the usual care group after controlling for confounders (P = 0.05). There were no significant differences in blood pressure, weight, or waist circumference at 12 months between groups.

CONCLUSIONS—A culturally adapted nurse-CHW team intervention was able to significantly improve diabetes control in the U.S. Territory of American Samoa. This represents an important translation of an evidence-based model to a high-risk population and a resource-poor setting.

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he Native Hawaiian and Other Pacific Islander group was one of the fasting growing ethnic groups between the 2000 and 2010 census, and Samoans are the second largest Native Hawaiian and Other Pacific Islander group in the U.S. (1). Samoans have remarkably high levels of obesity, type 2 diabetes, and other cardiovascular risk factors, which have increased

in the past 30 years (2). In the U.S. Territory of American Samoa (AS), the prevalence of type 2 diabetes in adults age 18 years and older is 21.5% (3) compared with 11.3% for adults age 20 years and older in the U.S. (4).

Translation research aims to apply interventions from previous efficacy studies to reduce health disparities in at-risk,

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resource-poor, and underserved communities (5). The AS health disparities are associated with its geographic isolation and history, but they are similar to other populations experiencing an increase in noncommunicable diseases and biobehavioral risk factors (6). AS is located in the central South Pacific, ~2,400 miles Southwest of Hawaii, has a population of 55,519 (7), and 58% of families have incomes below the U.S. poverty level (8). AS is considered "medically underserved" and a "health professional shortage area" (9). With economic modernization, food choices in AS have changed from traditional plant-based and fish-based diets to greater reliance on imported and highly processed foods and fast foods, which combined with reduced subsistence activities and low physical activity levels increase noncommunicable diseases risks (2,10). These AS dietary, physical activity, and lifestyle attributes are broadly similar to those in many U.S. low-income and ethnic minority communities, such as Native Americans, Hispanics, and African Americans. Thus, translational research in AS may be generalized not only to other Polynesians but also to other vulnerable U.S. communities experiencing high health disparities.

Community health worker (CHW) interventions have been used for decades for diabetes self-management support, although few studies used randomized designs and sample sizes were small (11,12). We adapted Project Sugar 2 (PS2), a successful evidence-based nurse-CHW team intervention, that supported diabetes selfmanagement in a primary care setting in an African American population in Baltimore, Maryland (13,14). PS2 (13) showed significant reductions in emergency visits and glucose control for patients at higher risk. PS2 used best practices, including treatment algorithms, community outreach, one-on-one interventions, multiple contacts over time (11,12,15), and the theoretically grounded Precede-Proceed model (16).

Here, we report outcomes from our randomized controlled trial, Diabetes

Diabetes care in American Samoa: RCT results

Care in American Samoa (DCAS), which tests the effectiveness of a culturally adapted, primary care-based nurse-CHW team intervention to support diabetes selfmanagement on diabetes control compared with usual care. More details of our process of cultural translation can be found elsewhere (17).

RESEARCH DESIGN AND METHODS

Study design

Our study took place at the Tafuna Clinic (TC) of the AS Community Health Centers, Department of Health, AS Government. TC was the first federally qualified community health center in AS and provides primary care and health promotion activities.

We used cluster randomization by village of residence within the clinic's service area to assign individuals either to the nurse-CHW team intervention group (CHW group) or to a wait-list control group (usual care) that would receive the CHW intervention after 1 year. Twelve village units in the service area were matched into six pairs and randomized by the study statistician, based on size and proximity, so that intervention and control villages were not adjacent, thus limiting potential contamination.

Study sample

The sample was drawn from TC patient records. Eligibility qualifiers were broad and were as follows: age 18 years old or older; resident in service area; self-identify as Samoan; physician diagnosis of type 2 diabetes; mentally competent and able to consent; unlikely to leave AS for >4months; and no serious comorbid conditions (e.g., end-stage renal disease, cancer). If more than one person in a household had type 2 diabetes, then they were enrolled because analysis clustered on both household and village. TC staff contacted patients to present the study and obtain consent. Enrollment was performed on a rolling basis (from February 2009 to May 2010). Baseline and 12-month assessments were conducted in the patient's choice of English or Samoan; blinded assessments were not possible because of village-level randomization.

We estimated a sample size at 362, based on a projected difference between groups in HbA1c of 0.7% at 1 year (effect size from Sugar 1 trial (14), assuming mean HbA1c of 8.6% at baseline, based on local medical records). We found fewer diabetic patients at TC than expected (6) and extended recruitment to new patients after community screenings and confirmation of diagnosis with TC providers. We enrolled 86% of 312 eligible participants (Fig. 1), consisting of 268 participants, with 104 (93 households) in the CHW group and 164 (148 households) in usual care. Although the sample size was less than projected, we found higher HbA_{1c} levels and retained 91% at 12-month follow-up, with no difference in loss to follow-up between groups.

Intervention

Lost to follow-up

Deceased (2)

"too busy"(1)

Feeding tube (1)

Cancer diagnosis (1)

Dialysis (1)

Off island >4 mos (7)

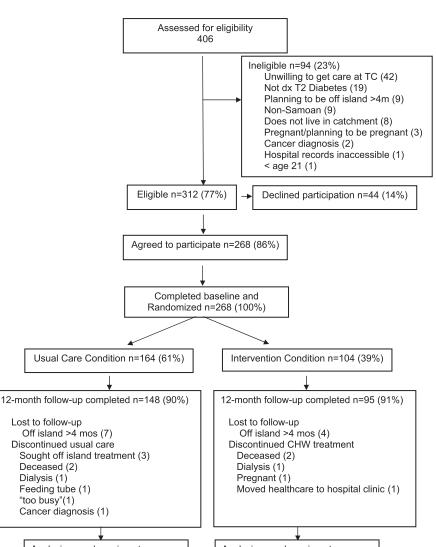
Sought off island treatment (3)

Analysis sample main outcome

n=164, intention to treat analysis

Discontinued usual care

Research staff included a nurse case manager (NCM) with registered nurse-level training and four CHWs with a minimum of high school education. Staff was hired early to help conduct formative focus groups and to develop the intervention. We trained both research and TC staff regarding research practice (value of research, randomization, contamination), standards of care, including American Diabetes Association guidelines (18), and the chronic care model (19), with emphasis on self-management support (20) and patient-centered communication skills (21). Research staff received additional extensive training regarding diabetes management, assessment techniques, and study protocols. An apprenticeship model was used when a new CHW was hired after the trial was underway. This involved a checklist of content areas to be covered in brief teaching sessions,



Analysis sample main outcome n=104, intention to treat analysis

Figure 1—*CONSORT diagram of recruitment and retention.* T2, type 2.

utilizing role plays, and by observation of other staff during their patient visits. All CHWs were certified regarding diabetes knowledge, blood glucose (BG), blood pressure (BP), and height and weight measurement procedures. A field director supervised the research staff, liaised with TC collaborators, and reported to the academic investigators. The NCM met with all patients at least once per year, conducted group sessions with patients at high risk, provided feedback to physicians about patient care needs, provided oversight of CHW visits, and approved visit progress notes. The CHWs helped patients make and keep health care appointments, helped patients understand diabetes, reinforced adherence to medication regimens, problem-solved barriers to self-care, provided support, and mobilized family support for diabetes selfmanagement.

As in PS2 (13), our intervention protocol was driven by a treatment algorithm that determined frequency and intensity of patient care, based on level of diabetes control and associated health risks. The algorithm prompted protocols for notification of medical personnel and to match self-management content to patient risk levels. The protocols were adapted because medical and professional resources were limited, and BG levels were higher in this population (6,22). Thus, our algorithm used higher cut-points. Risk profiles (Supplementary Table) were driven by HbA_{1c}, BP, smoking status, alcohol use, and Patient Health Questionnaire (PHQ-9) depression scores, based on baseline assessment data. All patients reviewed their risk profiles in an initial visit with the NCM and a CHW. The risk profile was placed in the medical chart for access by primary care providers. Patients at higher risk were seen weekly in a group meeting conducted by the NCM with CHW assistance or, if unable to attend the group meeting, they were seen individually by CHWs. Patients at moderate risk were seen monthly by CHWs and patients at lower risk were seen every 3 months. All individual visits occurred at the patient's home, workplace, or at TC, per the patient's choice. Family members were encouraged to attend these visits. BG and BP were monitored at each visit and urgent levels (BG >400, BP >200/120 mmHg) were referred immediately to the TC physician during clinic hours or to the hospital emergency department. At each contact, project staff also assessed for any serious adverse events (deaths, hospitalizations, actively suicidal status). If a serious adverse event occurred, then it was reported immediately to the TC medical director and to the study principal investigator (S.T.M.). Serious adverse events included 2 deaths in each study group, 12 hospitalizations in CHW group, and 17 hospitalizations in the usual care group. None was judged to be associated with the self-management support intervention.

Intervention content was guided by both patient risk and self-selected goals from a menu of the following eight topics: diabetes introduction; healthy eating; being active; using medication; monitoring (understanding and using information from BG and BP measurement, tracking progress); reducing risk (preventing complications, standards of care, visits and laboratory measurements, smoking, alcohol, foot care); healthy coping (managing stress and depression); and problemsolving (23). To facilitate CHWs teaching during their visits, we developed flip charts adapted from National Diabetes Education Program (24). The flip charts addressed all eight topics and integrated the Precede–Proceed model (16), as each topic had three sections for predisposing, enabling, and reinforcing factors. All study protocols were approved by Institutional Review Boards of AS and Brown University.

After the baseline assessment, both CHW and usual care participants received a copy of "Four Steps to Control your Diabetes for Life," in Samoan language, from National Diabetes Education Program (25). The CHW group participants were scheduled to have a first visit immediately, whereas usual care participants were told they would begin their program in 1 year. The risk profile also was prepared for the usual care group and was placed in medical charts; however, it was not discussed with patients by research staff. Usual care participants received one phone call at 6 months to update contact information, promote study retention, and identify adverse events that occurred since the baseline.

Measures

World Health Organization protocol was used for linguistic and cultural translation of instruments: forward translation; expert panel/back-translation; pretesting; and cognitive interviewing (26). This process confirmed that most of the translations were appropriate, with a few adapted items. Each translated measure was examined to determine if the original factor structure and subscales applied in this population.

Glycemic control was measured as HbA_{1c} to reflect BG over a 3-month period, using DCA 2000+ analyzer (27,28). The DCA 2000+ reports only ">14" for HbA_{1c} values >14. We had eight such values, and these were coded as 14; therefore, the mean HbA_{1c} is conservative. Three measurements of sitting systolic BP and diastolic BP were taken using standard American Heart Association protocol and they were averaged (29). Height, weight, and waist circumference were measured following standard methods (30).

We obtained church affiliation because participants attending church in a village randomized to the opposite trial arm were considered at risk for contamination. We found 80% of CHW and 47% of control group participants with opposite village church attendance. Self-reports of previous doctor visits and presence of comorbid conditions during the year before baseline were included as possible HbA_{1c} change moderators.

Dietary intake was assessed with a validated Samoan food frequency questionnaire (10). We adapted the Hill-Bone High Blood Pressure Therapy Scale (31) to assess medication adherence. Most responses to the 4-point Likert scale were limited to two responses, "none of the time" and "some of the time;" therefore, we created a dichotomous variable: "adherers," reporting none of the nonadherence behaviors versus "nonadherers," reporting one or more of the behaviors (32). Three individuals at baseline and three others at follow-up were not using medication with medical approval. Physical activity was measured using the World Health Organization STEPS interview items (33) about moderate and vigorous activity levels while working, leisure time, and transport during a typical week, which estimated metabolic equivalent (METs), and standard categories: low (<600 MET min/week); moderate (600-1,500 MET min/week); and high (>1,500 MET min/week) (33); we dichotomized METs to low and moderate/high.

The study assessed several psychosocial measures that were considered possible confounders if scores were correlated with treatment outcome (HbA_{1c}) or were unbalanced as a result of randomization. These included an adapted measure of diabetes beliefs (subscales: perceived diabetes control, benefits of diabetes control) (34) and the Patient Activation Measure (35).

Statistical analyses

Differences between treatment groups on baseline demographics and biological and behavioral measures were assessed using graphical methods and nonparametric and parametric tests as appropriate (e.g., Wilcoxon rank-sum test, *t* tests, χ^2 tests). For the primary outcome, HbA_{1c}, unadjusted means, quintiles, ranges, and SDs were examined and summarized overall and by treatment arm.

Using a mixed-effects longitudinal regression model (36) using SAS proc MIXED, we assessed whether there were between-group differences in mean outcome (HbA_{1c}) at follow-up, controlling for baseline outcome values as well as covariates (indicators of potential contamination by church, comorbidities, perceived diabetes control, benefits of control, Patient Activation Measure, history of doctor visits, gender, age, baseline risk level). Models included random intercepts to account for within-subject correlation between repeated outcomes over time and SEs were adjusted to account for two levels of clustering: households within villages. All analyses were conducted on the intent-to-treat sample, thus including all participants randomized at baseline (N = 268). In mixed-effects analyses, information from the observed data are used to provide information about the missing data, but missing data are not explicitly imputed (37). Mixedeffects models use a likelihood-based approach to estimation and therefore made use of all available data without directly imputing missing outcome values.

In addition to examining statistical significance in HbA1c change, we assessed potential between-group differences in meeting an important threshold for clinically significant change in HbA_{1c}, defined as a decrease in HbA_{1c} of at least 0.5% from baseline to 12 months (38). Using a longitudinal regression model implemented with generalized estimating equations (SAS proc GENMOD) (39,40) with robust SEs, we regressed binary indicators of meeting this change threshold on treatment assigned (CHW versus usual care), baseline level of HBA1c, and covariates (as listed previously) using binomial errors and a logit link function. Models adjusted for the two levels of clustering (households within villages) and a working exchangeable correlation structure were chosen to accommodate within-subject correlation.

Using a similar set of longitudinal models, we assessed whether key baseline variables (age, potential for church contamination, and baseline risk level) were moderators of the treatment effect on outcome (both absolute scores of HbA_{1c} and the binary indicator of making at least a 0.5% change in HbA_{1c} over time). Potential moderators were chosen a priori if they were baseline variables that represented subgroups of the population that potentially could be differentially affected by the intervention (i.e., age) or baseline variables known to be associated with the

outcome (i.e., risk level). Models included main effects of treatment and the potential moderator, as well as the interaction between them.

To assess the intervention effect on secondary outcomes (BMI, waist circum-ference, and BP), we fit a similar series of linear mixed-effects models to those described in the analysis of the primary outcome. All analyses were conducted in SAS 9.3 and significance level was set a priori at 0.05.

RESULTS—Table 1 presents baseline characteristics of each group. Mean age was 55 (SD = 12.7) years, most were participants

Table 1—Baseline characteristics

	CHW group (<i>n</i> = 104)	Usual care (<i>n</i> = 164)	Total (N = 268)
Demographics			
Age, mean (SD)	56 (12.5)	54 (12.9)	55 (12.7)
Married/with partner (%)	79	78	78
Education years, mean (SD)	12.6 (2.3)	12.4 (2.2)	12.5 (2.2)
Females (%)	57	65	62
Employed (%)	44	40	41
Church attendance in opposite village (%)	79.8*	47.0	59.7
Biological measures			
HbA _{1c} , mean (SD)	9.6 (2.1)	10.0 (2.3)	9.8 (2.2)
Current daily smoker (%)	10	7	8
Consumed alcohol in past 12 months (%)	6*	1	3
Depression symptoms/PHQ-9, mean (SD)	2.6 (2.4)	2.3 (1.7)	2.4 (1.9)
Algorithm risk levels (%)			
Low (quarterly visits)	10	12	11
Moderate (monthly visits)	49	37	42
High (weekly visits)	41	51	47
BMI (kg/m ²), mean (SD)	35.6 (6.5)	36.3 (7.8)	36.0 (7.3)
Systolic BP, mean (SD)	132 (17.4)	134 (17.4)	133 (17.4)
≥140 (%)	35	41	38
Diastolic BP, mean (SD)	84 (7.8)	84 (11.1)	84 (9.9)
≥90 (%)	24	35	31
Waist circumference, mean (SD)	118 (18.8)	121 (16.6)	120 (17.5)
Comorbid condition (% any)	15	10	12
Behavioral measures			
Medication adherence (%)	41	57	51
Calories from fat (>35%) (%)	67	62	
Physical activity level (moderate/high, ≥600 MET min/week) (%)	45*	49	
Selected psychosocial variables			
Benefits of diabetes control			
(0–5 scale), mean (SD)	4.8 (0.49)*	4.3 (0.45)	4.4 (0.48)
Belief "I am in control of my diabetes"			
(0–5 scale), mean (SD)	3.0 (1.09)*	3.6 (0.93)	3.7 (1.00)
Patient Activation Measure			
(0–100 score), mean (SD)	83.3 (18.9)*	74.5 (19.1)	77.9 (19.4)
Doctor visits for diabetes in past 12 months, mean (SD)	3.2 (2.68)*	5.2 (4.78)	4.4 (4.21)

*Significant difference by trial arm at baseline (P < 0.05).

were female (62%), with 12.5 (SD = 2.2) years of education, and less than half were employed (41%). The CHW group participated in significantly less physical activity and consumed more alcohol. Because both of these variables also were significantly correlated with risk level (P < P)0.05), we chose to include risk level in the final outcomes model. There also were significant differences between groups at baseline regarding number of doctor visits during the past year, belief in perceived diabetes control, belief in benefits of diabetes control, and Patient Activation Measure. In addition, 51% reported nonadherence in prescribed medications, 36% reported <35% of calories from fat, and 48% reported engaging in at least moderate physical activity at baseline. Mean HbA1c at baseline was 9.8% (SD = 2.2%) and 91% of participants had available HbA1c data at follow-up (no differential in missing information by treatment arm).

The CHW group received 74% of expected visits on average across all risk levels. HbA_{1c} at end of treatment was significantly lower in the CHW group compared with the usual care group when adjusting for baseline HbA1c levels, clustering, and potential confounders (b =-0.53; SE = 0.21; P = 0.03). The unadjusted HbA1c levels at follow-up were 9.3% (SD = 2.0%) in the CHW group and 10.0% (SD = 2.3%) in the usual care group. The model-adjusted average HbA_{1c} among CHW participants was 0.53 units less at the end of treatment compared with the usual care group when controlling for confounders (Table 2). As a subsequent step, we removed nonsignificant covariates from the model, and because there was no significant impact on the intervention effect and model fit was better for the full model, we chose to retain these additional effects.

Results indicate that 42.1% of CHW participants made a clinically significant change in HbA_{1c} (decrease at least 0.5%) versus 31.8% of usual care participants (unadjusted proportions). Model results suggest that there was a significant association between treatment assignment, i.e., CHW versus usual care, and the likelihood of making a clinically meaningful change in HbA_{1c} (b = 0.73; SE = 0.38; odds ratio = 2.07; 95% CI, 1.00-4.34; P = 0.05). The odds of reporting a change of at least 0.5% in HBA1c from baseline to end of treatment for the CHW participants was 2.07-times the odds among usual care participants.

Table 2—Regression coefficients from mixed-effects model for HbA_{1c} at 12-month follow-up

Variable	b	SE	Р
Intercept	4.00	1.46	0.02
Baseline HbA _{1c}	0.69	0.07	< 0.01
Treatment group (CHW vs. usual care)	-0.53	0.21	0.03
Indicator of potential for contamination by church	0.23	0.20	0.27
Perceived diabetes control	-0.07	0.11	0.56
Benefits of diabetes control	0.06	0.25	0.82
Patient Activation Measure score	0.0004	0.02	0.98
History of doctor visits (square root-transformed)	0.10	0.10	0.35
Indicator of comorbidities	0.48	0.31	0.15
Gender	-0.04	0.20	0.84
Age	-0.02	0.01	0.02
Low risk	-0.03	0.45	0.95
Moderate risk	-0.03	0.30	0.93

b, regression coefficient.

Clinically significant changes in HbA_{1c} were greater among participants at higher risk, with unadjusted values of 69.2% in the CHW group versus 40.8% in usual care. Model results indicate that the effect of treatment on the probability of making a clinically significant decrease was moderated by risk level at baseline $(b_{\text{treatment}} \times \text{risk} = 1.70; \text{ SE} = 0.67; P =$ 0.01). Among participants at high risk, the odds of making a change of at least 0.5% in HbA_{1c} in the CHW group was 5.4-times the odds among usual care participants. No significant association was found among participants at lower risk. Complete details are presented in Table 3. Analysis did not suggest any other significant moderators of the treatment effect on absolute HbA_{1c} scores at the end of treatment.

Analysis of secondary outcomes (BMI, waist circumference, and BP) did not reveal any significant between-group differences.

CONCLUSIONS—This study showed effectiveness of a nurse-CHW team self-management intervention to improve

diabetes control in a population at very high risk and from a resource-poor setting. The adjusted difference in HbA_{1c} was 0.53% between the CHW and usual care groups, after controlling for confounders, and this benefit was found across all risk levels in the CHW group. In addition, the odds of achieving a 0.5% clinically significant reduction in HbA_{1c} were double for the CHW group compared with usual care. This benefit was moderated by risk level, with participants at higher risk (47% of the sample) much more likely to experience a clinically significant reduction, as observed in PS2 (13). Our findings support our main hypothesis that the nurse-CHW team intervention would significantly improve diabetes control compared with usual care. Although previous reviews of CHW interventions point to the value of improved cultural competency and access for underserved populations, they often have shown mixed evidence for behavior change and outcomes (11,12). This study adds to the growing literature on the ability of CHW to improve HbA_{1c} (41) and adds to the number of CHW studies with more

Table 3—Risk as a moderator of the intervention effect on making a clinically significant change in HbA_{1c}

	OR	95% CI
High risk (CHW vs. usual care)	5.40	1.95-14.99
Low/moderate risk (CHW vs. usual care)	0.99	0.37–2.65

Model controlled for baseline HbA_{1c} , church attendance in opposite village, comorbidities, perceived diabetes control, benefits of control, Patient Activation Measure score, history of doctor visits, gender, age, and main effect of risk. OR, odds ratio; 95% CI, 95% confidence interval for the OR. rigorous randomized controlled designs (13,14,41).

There were no significant changes in BP, weight, or waist circumference. Almost three-quarters of expected visits occurred across all risk levels in the CHW group, indicating high internal validity for delivery of the algorithmbased protocols. Many CHW interventions use group-based models, yet these often result in lower attendance, thus limiting treatment dose (11). Our study primarily used individual or family home visits, and when group visits were offered to participants at higher risk, only 21% of their visits were in group sessions. We believe flexibility of using both individual and group visits facilitated delivery of a higher treatment dose. We could not examine a dose-response mechanism for change in HbA_{1c} because the visit frequency was based on risk level, and risk level was used as a moderator in outcome analyses. In future work, we will explore other mechanisms of change, including content of CHW visits and mediation analysis changes in the measured behavioral and psychosocial variables related to the Precede-Proceed model.

Strengths of this study included the use of evidence-based intervention features such as the treatment algorithm, community outreach, one-on-one intervention, multiple contacts over time (12,15), and application of behavior change theory (16). The CHW outreach approach was particularly useful in this resource-poor setting with limited health professional availability (9) and limited access, because even modest copays for health care visits and medications are difficult for many people with low incomes (17). CHW visits permit additional contact with the health care system and help patients make the most of health professional visits. This cultural context and setting required important adaptations to the evidence-based model we selected from PS2 (13), including algorithm adaptations to accommodate the higher-risk population. Our CHWs had more responsibility to provide diabetes self-management support, given low access to professional diabetes educators; however, they were supervised by a NCM and their interactions were guided by culturally and linguistically adapted materials.

Despite our enthusiasm about the statistically and clinically significant changes in HbA_{1c} in the CHW group, both groups had high mean HbA_{1c} levels at baseline and follow-up. These levels

reflect the broader difficulties Samoan patients have in managing their diabetes, in their community and health care system, and in the structural influences of the recent rapid increase in noncommunicable diseases and associated low health literacy (2,3,7,11). One implication for future studies is that a longer and more intensive behavioral self-management intervention may be necessary to achieve lower HbA_{1c} levels. An implication for clinical practice in AS and other low-resource settings is that concerted efforts to implement the chronic care model must continue (21).

We note several limitations. First, there were unplanned changes to our recruitment protocol because of the low number of patients with diagnosed diabetes at TC. The community screenings to identify undiagnosed cases were conducted in churches, workplaces, and other organizations. Our staff understood that more recruitment numbers were needed, but balance in group numbers got lost in this process. We attempted to statistically control for a number of potential biases, including clustering of family members and church membership across villages, but there may be other unmeasured biases. Our assessments and medical providers were unblinded because randomization was by village, which was the only practical way to randomize in this small geographic area with hierarchical family and village structures. The final recruitment numbers were less than expected for the sample size projected for statistical power. However, 86% enrollment of those eligible and 91% study retention suggest the sample is generalizable to the community from which it was drawn. We believe the findings here also may be generalizable to other diabetic patients in resourcepoor and high-risk populations.

Our randomized trial of a primarycare based nurse-CHW team intervention showed statistically significant improvements in HbA_{1c} and twice the odds of a 0.5% clinically significant decrease in HbA_{1c} in the CHW group compared with usual care. The strengths of this study included use of an algorithm-based treatment protocol that yielded a high treatment dose and culturally adapted intervention flipcharts to guide the CHW-delivered self-management education. This study adds to the growing body of evidence showing the ability of CHWs to improve diabetes outcomes and related behaviors. It also contributes to

the translation research movement to bring more evidence-based practices to underserved communities to reduce health disparities.

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J.D.D. conceptualized the project intervention and translation approach, supervised the implementation, and led the writing team for the manuscript. S.D. conducted the statistical analysis and wrote the statistical plan and results sections. A.D.S. prepared the data and data tables and contributed to editing. J.B. conceptualized the statistical plan and contributed to editing. R.K.R. led the qualitative phases of the study and edited the manuscript. M.G.G. conducted provider training and reviewed and edited the manuscript. O.N. and J.T. were American Samoa partners who helped oversee implementation and reviewed and edited the manuscript to insure validity in the local cultural context. S.T.M. was principal investigator, wrote the background on epidemiology and culture, and edited the manuscript. S.T.M. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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