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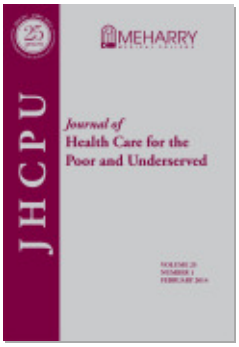


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# Improvement in Surrogate Endpoints by a Multidisciplinary Team in a Mobile Clinic Serving a Low-income, Immigrant Minority Population in South Florida

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*Abstract:* To determine effect on surrogate endpoints for cardiovascular disease (CVD), we performed a retrospective chart review of 114 patients seen by a multidisciplinary team that provided primary care services in a mobile clinic over 12 months. Eligible patients had outcomes available for at least six months. Mixed effect modeling examined variation in surrogate markers for CVD: blood pressure (BP), heart rate, and body mass index. Repeated measures ANOVA compared lipids, hemoglobin A1c, and medication use from baseline and throughout study. Most patients were female (75%), Haitian (76%), and low-income ($747/month) with average age 63 years. Common diagnoses were hypertension (82%) and hyperlipidemia (63%). Significant reduction in systolic BP, total- and LDL-cholesterol, and hemoglobin A1c were found ($p<.05$). Use of ACE-inhibitors, beta-blockers, diuretics, aspirin, metformin, and statins increased significantly ($p<.05$). Mobile clinic with a multidisciplinary team improved surrogate endpoints over 12 months in underserved, low-income, mostly foreign-born, Haitian population in U.S.

*Key words:* Disease management, Haitian, mobile health units, pharmacists, hypertension, hyperlipidemia, diabetes mellitus, multidisciplinary team, intervention, mixed effects modeling.

Of the Haitian population in U.S., 43% are foreign-born and of these, 46% live in Florida—the largest Haitian immigrant settlement in America.[1] Most minority communities including this population have health care barriers, compounded by immigrant-specific challenges, which lead to significant health disparities in preventive care and management of chronic disease.[2,3] The primary objective of this study was to determine the effect of a multidisciplinary team on surrogate markers for cardiovascular disease among low-income, immigrant patients seen in a mobile clinic from baseline and over 12 months. The secondary objective was to compare differences in these markers between Haitians and non-Haitians.

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## Methods

MediVan Health and Community Services, Inc., a 501(c)(3) nonprofit organization provided health and social service programs for medically-indigent adults in Broward County, Florida. Any person 55 years or older with an annual income of 150% of federal poverty level or less were eligible to receive care free-of-charge. Medical services included physical exams, laboratory analysis, health education, nutrition counseling, follow-up visits, and referral to specialty care providers. Provision of care occurred in a 36-foot recreation vehicle, or MediVan, which consisted of two examination rooms with standard medical supplies and diagnostic equipment.

Medical care was provided by an all-volunteer staff, including 14 physicians, 11 nurses, one nutritionist, and two translators; an ambulatory care residency-trained clinical pharmacist joined the team in January 2003. MediVan visited same community sites and patients attended an assigned site every month. Removal from the clinic occurred if the patient missed three consecutive visits.

Multidisciplinary treatment plans included selection and adjustment of drug therapy such as adding/removing medications, adjusting dose and/or interval, calculating insulin dosages, ordering laboratory analysis and selecting cost-effective medications. Available guidelines for hypertension,[4] hyperlipidemia,[5] and diabetes[6] were used to guide recommendations. Patient education was provided aloud and/or in written formats with translators and included medication adherence counseling, strategies for managing side effects of medications, disease-related education, patient-centered strategies for lifestyle changes, point-of-care, and importance of completing laboratory requests.

Medications were purchased from pharmacies by MediVan Project or obtained from manufacturers' patient assistance programs; over-the-counter medications were purchased by patients. Most costs were paid by grant support and collaborative partners.

Upon approval by institutional review board, data was retrospectively collected for patients seen January 2003 through May 2008. Baseline was time pharmacist first participated in patient care (patients could already be clinic members). Age, gender, ethnicity, income, systolic blood pressure (SBP), diastolic BP (DBP) heart rate (HR), weight, lipid panel, hemoglobin A1c, medical- and medication histories were obtained. Clinic history (number of months patients in clinic prior to pharmacist integration) and clinic attendance (number of months patients attended clinic during study period) were also documented. SBP, DBP, HR and weight were collected at three, six, nine and 12 months and lipid panel, hemoglobin A1c and medication use at six and 12 months.

Patients were included in analysis if they actively attended MediVan for six months or longer after their first encounter with a multidisciplinary team that included a pharmacist. Missing values were imputed using last-observation-carried-forward method if last value was within the previous three-month period. Patients were excluded from individual outcome analyses if vital signs or weight data were unavailable four or more consecutive months or laboratory values were unavailable eight or more consecutive months.

**Statistical analysis**. Mixed effect modeling was used with factors time-point (three, six, nine, or 12 months from baseline), ethnicity (Haitian, non-Haitian), type 2 diabetes mellitus (T2DM), hyperlipidemia (HL) as fixed effects and subject as random effect

in covariance model. Primary outcome measures SBP, DBP, HR and body mass index (BMI) were dependent variables. Age, income, clinic history and clinic attendance were covariates. Newton-Raphson algorithm solved restricted maximum likelihood equations. Diagonal matrix time covariance pattern was specified. As per model and unless otherwise specified—age, income and clinic attendance were maintained at means: 62.8 years, 54% of poverty level and 87%, respectively; number of months patients participated in clinic prior to pharmacist integration was maintained at 41 months.

Sensitivity analysis was used to test model in response to changes in covariates from mean value. Covariates were examined at following levels: income (0%, 25%, 100%), age (20, 40, 80 years), attendance (0%, 25%, 50%, 100%) and prior history at clinic (0, 24, 108 months). For secondary outcome, Haitian sub-population was examined, and mixed effects model specified above was used with ethnicity term removed. All aforementioned statistical analyses were performed with NCSS version 7.1.21 (Kaysville, UT).

Repeated measures analysis of variance (RANOVA) method was used to compare overall effect of continuous outcomes (laboratory parameters, medications) over time. Sphericity was assumed unless Mauchly's test failed ($p<.05$). If this assumption was violated, degrees of freedom were corrected using either Greenhouse-Geisser estimates if epsilon $\leq .75$ or Hyunh and Feldt if $>.75$. Using Bonferroni correction, paired Student t-test was used to run post-hoc pairwise comparisons between all time-points. Alpha of 5% used to determine significance for all comparisons. SPSS version 18 (Somers, NY) used to run RANOVA.

## Results

The multidisciplinary team provided care to 135 patients with 114 meeting criteria for inclusion in analysis. One hundred five patients were already active participants in clinic prior to pharmacist integration (mean $\pm$ SD duration 40 $\pm$ 37months); nine participants became MediVan patients after pharmacist joined the team. Eighty-eight patients were seen for 12 months and 26 for 6–11 months. Patients attended 87% of scheduled visits. Most patients were foreign-born, non-English-speaking females of Haitian origin with low socioeconomic status and high prevalence of hypertension (HTN) and HL (Table 1). Average number of chronic conditions/patient was 1.4 $\pm$ 0.95.

Physical exam data were available for most patients (82%) at all time-points. Of 93 patients with HTN, data from three Haitian patients were considered outliers (SBP$\geq$200 mmHg) and removed from analysis. Analysis was performed with and without outliers and effect of outliers was to increase power of our findings; thus, our results as stated are conservative estimates. Mixed model analyses of data from remaining 90 patients indicated time-point ($p=.002$), ethnicity ($p=.04$) and age ($p=.006$) were significantly related to change in SBP. After adjusting for age, income, clinic attendance and clinic history, significant change in SBP occurred over 12 months (baseline: 136 mmHg (95% Confidence Interval: 131, 141); three months: 130 mmHg (95% CI: 126, 136); six months: 132 mmHg (95% CI: 127, 137); nine months: 126 mmHg (95% CI: 122, 132); 12 months: 134 mmHg (95% CI: 129, 139), $p=.002$) and specifically at month nine (change from baseline $-10$ mmHg, $p=.0003$) in pairwise comparisons using Bonferroni

## Table 1.

### BASELINE CHARACTERISTICS (N=114)

| | |
|---|---|
| Age, mean ± SD, years | 63 ± 11 |
| Women, n (%) | 85 (75) |
| Ethnicity/Race, n (%) | |
| Haitian Origin | 87 (76) |
| Hispanic Origin | 11 (10) |
| Non-Hispanic White | 4 (3) |
| Black (non-Haitian or non-Hispanic) | 12 (11) |
| Monthly Income, mean ± SD, $ | 747 ± 590 |
| No income to report, n (%) | 38 (33) |
| Smokers, n (%) | 6 (5) |
| Co-morbidities | |
| Hypertension, n (%) | |
| All diagnosed patients | 93 (82) |
| Haitian patients | 74 (80) |
| Hyperlipidemia, n (%) | |
| All diagnosed patients | 72 (63) |
| Haitian patients | 53 (74) |
| Diabetes mellitus, n (%) | |
| All diagnosed patients | 47 (41) |
| Haitian patients | 37 (79) |
| Gastro-esophageal reflux disease, n (%) | |
| All diagnosed patients | 26 (23) |
| Haitian patients | 21 (81) |
| Arthritis, n (%) | |
| All diagnosed patients | 39 (34) |
| Haitian patients | 28 (72) |

SD = Standard Deviation

correction. Ethnicity affected SBP over time as throughout 12 months, non-Haitians had SBP 9 mmHg lower than Haitians (p=.04) (Figure 1). Although SBP was higher for Haitians than non-Haitians at any timepoint, drop in SBP in Haitian patients did occur (change in SBP from baseline to months three, six, and nine were −6 mmHg, −6 mmHg, and −10 mmHg, respectively; all p≤.02). Of 71 Haitian patients with HTN, 13 had T2DM, 23 had HL, 20 had both T2DM and HL, and 15 had HTN only. During study period, patients with concomitant HL and T2DM had higher SBP compared with those with HTN alone, HTN and HL or HTN and T2DM (p=NS, Figure 2).

Of 90 patients with HTN, 34 were seen for 14 months or less and remainder participated in clinic 24–108 months prior to pharmacist integration. Sensitivity analysis using mixed model found length of time at clinic prior to pharmacist integration,

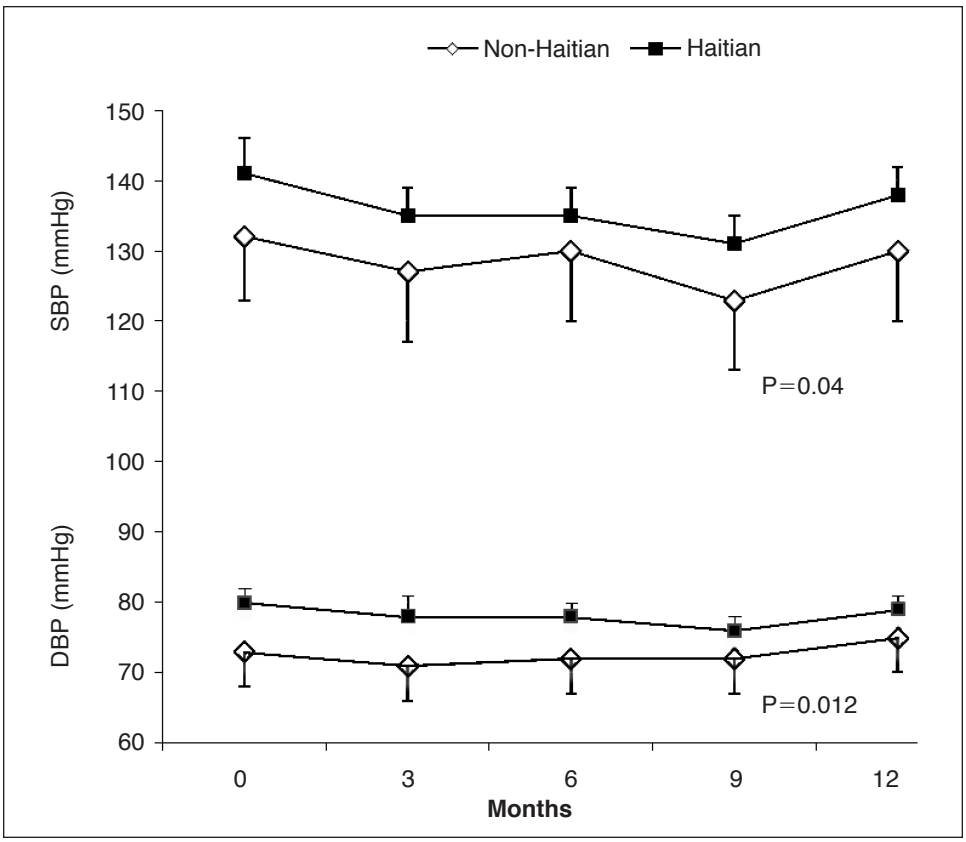


Figure 1. Average systolic and diastolic blood pressures (adjusted means ± 95% confidence intervals) were consistently higher among Haitians (n=71) compared with non-Haitians (n=19).

reduction in attendance rate from 87% to 50% and then to 25%, and poverty level (reduced to zero income) had no significant effect on SBP. HR (67–74 bpm) and DBP (72–79 mmHg) remained unchanged over 12 months. However, after controlling for age, income, clinic attendance and history, Haitians had DBP 5 mmHg higher than non-Haitians throughout study period (p=.012) (Figure 1).

BMI remained unchanged over 12 months (25–28 kg/m$^2$) although BMI was associated with age (p<.001). Based on the model, BMI decreased by 0.2 kg/m$^2$ for every year of increase in age (p=.0003). After adjusting for age, income, attendance and history, Haitian women had higher BMI than Haitian men (3.0 kg/m$^2$, p=.025).

Analyses showed total (p=.0001) and LDL-cholesterol (p=.0007) were significantly reduced over 12 months and reductions were significant at months six and 12 *versus* baseline (p<.05) (Table 2). Values decreased for triglycerides and increased for HDL, but were non-significant. Subgroup analysis showed average triglyceride values lower among Haitians (n=22) *versus* non-Haitians (n=6) (baseline: 101 mg/dL, six months:

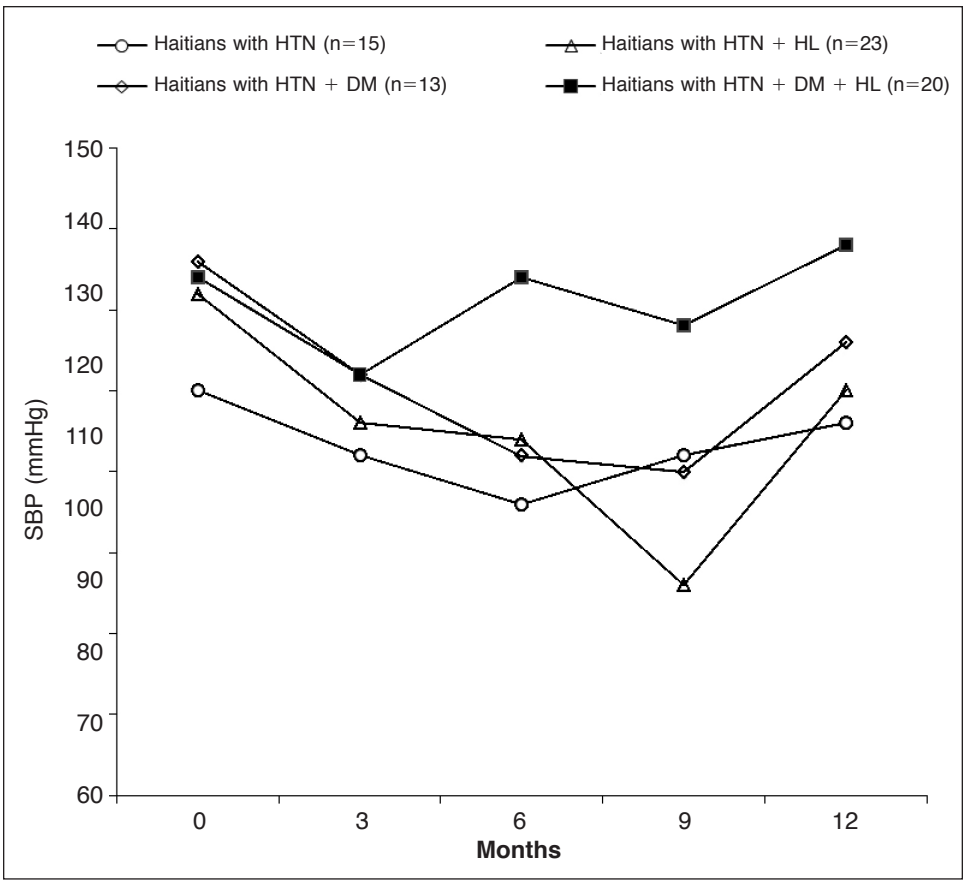


Figure 2. Least-squares adjusted mean systolic blood pressure was consistently higher among Haitians with hypertension and concomitant hyperlipidemia and type 2 diabetes mellitus.

94 mg/dL, 12 months: 99 mg/dL, p=.04). For patients on statins, 12 had increased creatine phosphokinase levels (200–600 IU/L). Of these, statins were discontinued in four symptomatic patients, continued in five asymptomatic patients, dose reduced in one patient, and two patients were lost to follow-up. All hemoglobin A1c values were from Haitian patients and significantly reduced over time (p=.002) with reduction approaching 1% at months six and 12 *versus* baseline (Table 2).

Data about medications were available for 90% of patients (Table 3). Drugs were grouped and analyzed by class. Use of BP medications increased significantly for ACE-inhibitors (mostly lisinopril), beta blockers (atenolol, propranolol and metoprolol) and diuretics (mostly hydrochlorothiazide) (p<.005) but was reduced for calcium channel blockers (mostly amlodipine, verapamil, nifedipine), over 12 months (p=.038). Use of aspirin, metformin, statin (mostly simvastatin) and PPI (mostly pantoprazole or omeprazole) also increased significantly (p<.0005) but remained unchanged for

## Table 2.

### LABORATORY VALUES AT BASELINE AND FOLLOW-UP TIME-POINTS USING REPEATED MEASURES ANOVA (DATA PRESENTED AS MEANS [95% CI])

| Parameter | Baseline | 6 months | 12 months | p-value[a] | Baseline versus 6 months[b] | Baseline versus 12 months[b] |
|---|---|---|---|---|---|---|
| TC (mg/dL) (n=28) | 206 [197, 215] | 176 [167, 185] | 177 [168, 186] | .0001 | −31[c] [−46, −15] | −29[c] [−44, −14] |
| LDL-C (mg/dL) (n=28) | 126 [118, 136] | 103 [94, 112] | 100 [91, 109] | .0007 | −24[c] [−38, −9] | −26[c] [−41, −12] |
| HDL-C (mg/dL) (n=28) | 52 [50, 54] | 54 [52, 56] | 55 [53, 57] | .08 | 2 [−1, 5] | 4 [.09, 7] |
| TG (mg/dL) (n=28) | 130 [117, 143] | 115 [102, 128] | 110 [97, 123] | .08 | −15 [−36, 6] | −21 [−41, 0.1] |
| HbA1c[d] (%) (n=22) | 8.20 [6.19, 10.2] | 7.55 [5.54, 9.55] | 7.30 [5.30, 9.30] | .002 | −0.92[c] [−0.86, −.99] | −0.89[c] [−0.83, −.96] |

[a]Comparison of the overall effect across all timepoints
[b]Pairwise comparison using Bonferroni correction
[c]P<0.05
[d]Hemoglobin A1c values were log-transformed prior to analysis and subsequently back-transformed for presentation as circularity was violated.
TC = total cholesterol
LDL-C = low-density lipoprotein cholesterol
HDL-C = high density lipoprotein cholesterol
TG = triglycerides
HbA1c = hemoglobin A1c
CI = Confidence Interval

sulfonylureas, glitazones, non-steroidal anti-inflammatory agents (mostly ibuprofen, naproxen) and insulin.

Average number of medications/patient (mean ± SD) increased from 3.4 ± 2.0 at baseline to 4.3 ± 2.1 and 4.4 ± 2.1 at months six and 12, respectively (p<.0005). Haitians used more ACEI (baseline: 60%, six months: 73%, 12 months: 79%, p=.006) and diuretics (baseline: 72%, six months: 82%, 12 months: 85%, p=.001) than non-Haitians. Insulin and glitazone therapies were used solely by Haitian patients.

Hospitalizations were reported by four patients. A patient with atrial fibrillation was hospitalized twice, once for chest pain requiring carotid endarterectomy (four days) and another time for abdominal pain (four days). The second patient with a pacemaker was hospitalized for 10 days for syncope. The third patient was hospitalized one day for hypoglycemia and medications included sulfonylurea, metformin, and glitazone.

## Table 3.

### PROPORTION OF PATIENTS RECEIVING MEDICATIONS AT BASELINE AND FOLLOW-UP (N=103)

| | Baseline | Month 6 | Month 12 | p-value[a] |
|---|---|---|---|---|
| Angiotensin converting enzyme inhibitors | 56 (54%) | 68 (66%)[b] | 75 (73%)[b,c] | .005 |
| Aspirin | 10 (10%) | 24 (23%)[b] | 26 (25%)[b] | .005 |
| Beta blockers | 29 (28%) | 34 (33%) | 40 (39%)[b,c] | .005 |
| Calcium channel blockers | 22 (21%) | 27 (26%) | 18 (17%)[c] | .040 |
| Diuretics | 67 (65%) | 77 (75%)[b] | 80 (78%)[b] | .005 |
| Sulfonylureas | 24 (23%) | 28 (27%) | 28 (27%) | .150 |
| Glitazones | 12 (12%) | 14 (14%) | 13 (13%) | .350 |
| Insulins | 8 (8%) | 8 (8%) | 8 (8%) | — |
| Metformin | 24 (23%) | 33 (32%)[b] | 33 (32%)[b] | .005 |
| Non-steroidal anti-inflammatory drugs | 34 (33%) | 39 (38%) | 36 (35%) | .360 |
| Proton-pump inhibitors | 25 (24%) | 35 (34%)[b] | 41 (40%)[b,c] | .005 |
| Statins | 35 (34%) | 52 (50%)[b] | 54 (52%)[b] | .005 |

[a]Comparison of the overall effect across all time points
[b]Pairwise comparison of specified time point versus baseline, $p<.05$
[c]Pairwise comparison of 6 months versus 12 months, $p<.05$

The fourth patient was hospitalized for renal failure (four days) and stopped attending MediVan post-hospitalization.

## Discussion

This study evaluated surrogate endpoints of cardiovascular disease after delivery of free primary care by a multidisciplinary medical team in a mobile clinic serving predominantly low-income Haitians over 12 months. The most common diagnosis was HTN and SBP was significantly reduced by up to 7.4%, a maximum average of 10 mmHg. A 5-mmHg reduction in SBP is estimated to result in 14% overall reduction in mortality due to stroke, 9% reduction in mortality due to coronary heart disease and 7% reduction in all-cause mortality.[7] At baseline, 40% of our hypertensive patients had BP<140/90 mmHg and proportion increased to 59%, 57%, 73%, and 54%, at three, six, nine, and 12-months, respectively ($p<.001$ at month nine, compared with baseline). SBP reduction may have been due to increased use of anti-hypertensives, counseling on self-monitoring of BP with appropriate medication use, and direct questioning about medication adherence ("How do you remember to take your medications?" and pill counts) with assistance of Haitian Creole translators. Surprisingly, adherence to clinic

visits did not affect SBP, suggesting patients do not have to visit health care providers monthly. However, MediVan patients were required to visit monthly to verify efficacy and manage adverse events in a timelier manner as reliable telephone access was not guaranteed.

Subgroup analysis showed compared with non-Haitians, average BP was up to 9- and 5-mmHg higher for SBP and DBP in Haitians. A retrospective study from a South Florida public teaching hospital found, based on JNC V guidelines,[8] high prevalence and severity of HTN among Haitians (N=77).[9] Preston et al. reported 87.5% of Haitians had HTN and 77% were stage 2 or higher. Among the treated, 26% were controlled, 48% had evidence of target organ damage and 42% had severe non-compliance (defined as emergency room admission for severe uncontrolled hypertension or failure to follow-up in outpatient clinic on two consecutive occasions). Correspondingly, higher proportions of ACEI and diuretic use among Haitian patients in our study were a result of managing higher average BP. It remains unclear why reductions in SBP was significant only at month nine; possible reasons include non-adherence to pharmacological and non-pharmacological recommendations and external factors such as financial constraints (e.g., purchasing healthy, more expensive foods) or traveling to Haiti without medications.

Other observations included improvements in total- and LDL-cholesterol and hemoglobin A1c. Increased statin use resulted in average LDL-cholesterol of 100 mg/dL, with good overall tolerability. Although reduced, mean hemoglobin A1c at months six or 12 did not reach the goal of ≤7%. Several challenges occurred while managing MediVan patients. First, a small percentage of patients had appropriate laboratory follow-up. Although frequent reminders for blood work were provided, caregivers were not always able to take time-off from daily responsibilities to chauffeur patients to labs. Second, a patient with hemoglobin A1c of 16.6% already on maximum oral therapy refused insulin due to fears of hypoglycemia and subsequent death. Third, optimization of therapy was difficult due to cost of patented brand-name medications, insulins and glucose test strips.

An interesting finding was that Haitian females had higher average weight than Haitian males. National Health Interview Study data indicate that compared with U.S.-born White women, odds ratios of obesity is 2.09 (95% CI: 1.98, 2.21) for U.S.-born Black women and 1.22 (95% CI: 0.99, 1.51) for foreign-born Black women.[10] Compared with U.S.-born White men, odds ratios of obesity is 1.40 (95% CI: 1.31, 1.50) for U.S.-born Black men and 0.55 (95% CI: 0.43, 0.69) for foreign-born Black men.[10] Thus, being foreign-born seems protective for Black men but not women. Based on attendance history at MediVan prior to baseline, study patients had been living in U.S. for three years on average and may have assimilated to mainstream culture. Information on diet, exercise practices, and other behavioral characteristics would have provided additional insight.

**Limitations**. Due to its retrospective nature, this study has limitations. Lack of a control group and randomization prevented true effect of multidisciplinary team from being captured. Patients were recruited from predominantly Haitian sites and use of clinic services was voluntary. Therefore, this was a convenience sample and prevalence of illnesses observed may not reflect actual Haitian population in U.S. Improvements

in surrogate markers may be due to changes in care delivered outside MediVan Project during same time-frame. However, the office staff made every effort to verify patients did not receive care from another source. If a patient was found to have medical insurance, he/she were removed to allow another person access. Most patients seen were included in analysis however selection bias from investigator perspective may have occurred. Finally, investigators were dependent on availability and accuracy of medical records and patient-reported information. Future studies using more rigorous design (i.e., prospective, randomized) should assess lifestyle modification and medication adherence, quality-of-life, hospital admissions, and health care utilization costs in this population.

In conclusion, a mobile clinic with a multidisciplinary team providing primary care services showed improvement in surrogate cardiovascular endpoints over 12 months in an underserved, low-income, mostly foreign-born, Haitian population. Provision of medical care *via* a mobile clinic within the community allowed patients with high incidence of HTN, HL, and T2DM access to medical care, cardio-protective medications, along with ongoing reminders to maintain appropriate lifestyle modifications and medication adherence. Due to financial constraints, MediVan Project ended in August 2008 and clinic patients were referred to hospitals in the area for medical care.

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