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Effectiveness of a hypertension management protocol in rural Haitian adults and pregnant women

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ABSTRACT

Background: Haiti's hypertension prevalence among adults ≥40 years of age is nearly twice that of nations in the Americas. Haiti Health Initiative (HHI) developed a hypertension management protocol for use in outreach clinics in Timo, a rural mountainous community in Haiti. This study aimed to evaluate the effectiveness of the hypertension protocol for treating adults ≥40 years of age and pregnant women with severe hypertension.
Methods: This retrospective longitudinal study included 209 patients across 1148 clinic visits/encounters. De-identified medical records from 11 biannual outreach clinics between April 2014 to April 2019 were reviewed for analysis. Descriptive statistics, paired *t*-tests, and multilevel models were performed. The primary outcome was systolic and diastolic blood pressure measurements at each clinic visit.
Findings: In the study (n = 1148 visits), hypertension and severe hypertension prevalence were respectively 79·8% and 38·4%. Multilevel models showed a decrease of 0·29 mmHg ($p = 0·37$) in systolic blood pressure and a decrease in diastolic blood pressure of 0·66 mmHg ($p < 0·001$) per visit. Individual factors and protocol adherence did not predict a reduction in blood pressure.
Conclusion: Effective management of hypertension and other chronic conditions among hard-to-reach populations with limited healthcare access requires comprehensive outreach efforts that address care antecedents, structures, and processes. Although outreach clinics made treatment accessible to vulnerable populations, the protocol, which used medications with previously demonstrated efficacy, had little impact on reducing blood pressure in patients with severe hypertension.

1. Introduction

Based on the World Health Organization (WHO) definition of hypertension as a blood pressure (BP) ≥140/90 mmHg [1], Haiti's hypertension prevalence among adults over 40 years of age is estimated to be 40–70%, compared to 35% in the Americas, and 55% in Africa [2–5]. Haitians are of African descent, which has historically been associated with higher hypertension prevalence [1,6]. Another risk factor for hypertension in the Haitian population is a high salt diet which can be as high as 35 g per person per day [7–9]. Hypertension predisposes individuals to atherosclerotic, cardiovascular, cerebrovascular, and renal diseases and pregnancy complications such as preeclampsia and eclampsia [1,10]. Cardiovascular diseases are a leading cause of death in Haiti, with rates even higher than infectious diseases, including HIV-related deaths [11,12]. Coronary heart disease accounts for 15% of deaths in Haiti, and hypertension contributes to 3% of total deaths [13,14].

Hypertension management is multifaceted and combines pharmaceutical agents with lifestyle changes. Amlodipine is a safe, effective, and inexpensive calcium channel blocker commonly recommended for hypertension management among people of African descent and requires minimal laboratory monitoring [15–17]. Labetalol, a beta-blocker, is another antihypertensive agent with safety data in pregnancy, making it a preferred agent for women of reproductive age [15,18]. In addition to medications, exercising regularly and following the Dietary Approaches to Stop Hypertension (DASH) diet are

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recommended lifestyle changes to manage hypertension [7,19]. Although effective interventions exist, the Haitian population continues to experience hypertension-related complications [20]. The problem of effective hypertension management is compounded by socioeconomic conditions, geographic location, and limited access to available resources. The poverty rate in Haiti is 60%, and two-thirds of the people in poverty reside in rural areas [21]. Healthcare in Haiti is in short supply with only 0·8 hospital beds per 1000 people [8]. Despite these facts and statistics, there is a paucity of longitudinal studies on hypertension management and treatment effectiveness in the Haitian population.

Effective chronic disease management in resource-limited areas and among vulnerable or marginalized individuals, families, and communities begins by recognizing key factors that facilitate or hinder positive health outcomes. The Donabedian model of quality care with antecedents informed this study [22]. This model suggests that patient antecedents (factors such as age or past history), clinic structures, provider characteristics, and clinic protocols are significant determinants of health outcomes.

The goal of the United States-based nonprofit organization, Haiti Health Initiative (HHI), is to uncover root causes that contribute to reduced health and persistent poverty in rural Haiti. In collaboration with its sister organization in Haiti, Inisyativ Sante Peyzan (ISAP), they developed the Timo Protocol for Hypertension Management (TIP—H) for people living in and around the rural community of Timo, a remote and mountainous area in Haiti without access to essential health services [23]. The TIP-H focused on adults over 40 years and older because of the high prevalence of hypertension in this age group [2–5] and known complications in pregnancy [1,10]. It was implemented during biannual outreach clinics lasting one week in the spring and fall seasons.

The primary objective of this study was to quantitatively evaluate the impact over time of the TIP-H on the BP of Haitian adults with severe hypertension (≥160/100 mmHg) in Timo. Because we were using drugs known to reduce hypertension, our hypothesis was that we would see a reduction in blood pressure. We also evaluated clinicians' adherence to the protocol in different clinic stations. This study will increase knowledge concerning hypertension management among Haitians and other hard-to-reach individuals with severe hypertension, particularly those living in rural, remote, and resource-limited areas.

2. Methods

2.1. Study design

This study is a retrospective review of medical records from 11 biannual outreach clinics held from April 2014 to April 2019. Visiting clinicians such as nurses, nurse practitioners, physicians, physician assistants, pharmacists, and pharmacy technicians worked with Haitian nurses, community health workers (CHW), and interpreters to hold these biannual clinics. The authors received permission from HHI and ISAP to use de-identified data and ethics approval from Haiti's National Bioethics Committee and the University of Utah Institutional Review Board.

2.2. Timo hypertension management protocol

Haiti Health Initiative and ISAP developed the TIP-H based on published literature and national guidelines for diagnosing and treating high blood pressure; customized for the local community needs, safety considerations, and drug availability. The protocol (unpublished) was designed for use in three of the clinic stations:

1. In the *Triage Station*, a nurse or CHW measured the BP of all adults 40 years and older, those on a current antihypertensive medication, and pregnant women.
2. In the *Medical Station*, a medical provider performed a second BP check to verify the initial measurement for patients with BP ≥140/90 mmHg. A prescription for either amlodipine or labetalol was provided if both BP measurements were ≥ 160/100 mmHg.
3. In the *Pharmacy Station*, a pharmacist dispensed a one-month supply of antihypertensive medication in a tamper-resistant bottle free of charge (amlodipine 10 mg orally once daily or labetalol 100 mg orally twice daily for women of reproductive age). The CHW provided medication counseling, including a reminder to return to the Community Center monthly to check their BP and refill their prescription before the supply runs out.

Because professional medical providers were only available twice a year, at the biannual clinics, the protocol focused on treating adults with severe hypertension, defined as systolic blood pressure (SBP) ≥ 160 mmHg or diastolic blood pressure (DBP) ≥ 100 mmHg. Targeting patients with severe hypertension decreased the likelihood of hypotensive symptoms from the medications. Blood pressure measurements and dispensed medications were recorded.

2.3. Participants

Study participants were identified through review of the medical records. Participants included in the analysis (a) attended at least three biannual clinics, (b) had at least one BP measurement per visit, and (c) were at least 40 years old or pregnant women. Participants were excluded if they did not meet these criteria or had recorded BP measurements that were obviously inaccurate (outside of plausible range) and unverifiable (0.1%). Study criteria were designed to include participants who were treated per protocol and provide a longitudinal view of BP management in patients seen in the clinic.

2.4. Measures

Study outcome variables were SBP and DBP, measured at the Triage and Medical Stations using a manual sphygmomanometer. Explanatory variables included participants' age, sex, pregnancy status, antihypertensive medications dispensed per protocol at each clinic visit, and the overall number of clinic visits in the study time frame. An additional study outcome was clinician adherence to protocol based on information available in medical records.

2.5. Data collection procedures

Study data for this secondary analysis of medical records data were de-identified based on Safe Harbor de-identification criteria [24]. Blood pressure values were verified by comparing electronic files against paper medical records.

2.6. Data analysis

Quantitative analyses were performed using R Version 4·2·0. Hypertension prevalence rates were calculated for (1) all Haitian adults of both sexes who attended biannual outreach clinics from 2014 to 2019 and (2) participants who met study inclusion criteria. Descriptive statistics for study participants and clinician adherence to the hypertension protocol were summarized. Paired *t*-tests were conducted to compare SBP and DBP values at each participant's first and last clinic encounters. Linear mixed-effects models were applied to analyze predictors of change in SBP and DBP over time. Mixed-effects models (multilevel modeling) accounted for repeated measurements for the same participant over multiple clinic visits [25]. A *p*-value of 0.05 was considered statistically significant.

3. Results

3.1. Descriptive statistics

Tables 1-3 present descriptive statistics of categorical and continuous variables for study participants. Two-hundred and nine patients met study criteria where 60% of participants were female and 2·4% were pregnant. On average, patients attended clinic 5–6 times. The average BP for both male and female participants was 153/93 mmHg.

3.2. Prevalence of hypertension and severe hypertension

We calculated the prevalence of hypertension and severe hypertension for all patient data in the clinic database (n = 6633 clinic visits/encounters) from 2014 to 2019 and for participants in our study dataset (n = 1148 clinic visits/encounters). In the clinic database, hypertension prevalence was 44·3% for all adults ≥18 years of age who attended clinics. Severe hypertension prevalence with two BP measurements was 9·2%. In the analytic dataset, hypertension prevalence for adults ≥40 years of age and pregnant patients was 79·8% and severe hypertension prevalence was 38·4%.

3.3. Interindividual differences in change

Figs. 1 and 2 present individual smooth nonparametric trajectories (n = 209) in the study dataset with the bold line depicting an average change trajectory for all participants. Individual SBP and DBP were plotted and normalized for the clinic visit number, where 0 is the baseline visit, 1 is the second visit to clinic, and so forth. These graphs also indicate considerable interindividual heterogeneity in change. For some patients, SBP and DBP measurements moderately decline with each clinic visit; for others, the measurements remain stable; for some, the measurements increase.

Results of the paired t-test show the first SBP value (M = 153·4 mmHg, SD = 25·4 mmHg) and the last SBP value (M = 152·7 mmHg, SD = 25·4 mmHg), suggesting negligible improvement in participants' SBP over time (t(208) = 0.45, p = 0·65). Likewise, the first DBP value (M = 95·0 mmHg, SD = 15·2 mmHg) and the last DBP value (M = 93·2 mmHg, SD = 15·2 mmHg) indicate insignificant improvement in participants' DBP (t(208) = 1·79, p = 0·08).

3.4. Multilevel analyses

We performed analyses using maximum likelihood linear mixed-effects modeling to examine SBP and DBP values as dependent variables. SBP and DBP values collected at the point of care were time-unstructured and unbalanced. We fit several models to the sample SBP and DBP data beginning with the unconditional means and unconditional growth models. In regression models, individual factors (e.g., age, sex, pregnancy status, number of clinic visits) and protocol adherence (e.g., BP checks, antihypertensive medications received at each clinic visit) did not show any effect. Multilevel models included 1148 BP values for 209 study participants and showed an insignificant reduction in SBP by an average of 0·29 mmHg (p = 0·37) per visit. In contrast, DBP showed a statistically significant decrease by an average of 0·66 mmHg (p < 0·001) per visit. Analysis of a subset of participants who received antihypertensive medications (n = 202, BP values = 1118) showed an insignificant decrease in SBP by an average of 0·41 mmHg (p = 0·20) per visit. In contrast, DBP showed a statistically significant decrease by an average of 0·70 mmHg (p < 0·001) per visit.

Table 1
Characteristics of study participants.

	n	%
Total unique patients	209	..
Sex	..	..
Female	126	60·3
Male	83	39·7
Total visits	1148	..
Number of visits by age:	..	..
18–39 years	27	2·4
40–64 years	649	56·5
≥ 65 years	472	41·1
Pregnant patients	28	2·4
Patients who received antihypertensive agents	202	96·7
Number of antihypertensive prescriptions dispensed	601	..

Table 2
Descriptive statistics for participants' age and number of clinic visits.*

	Mean	SD	Median	Minimum	Maximum
Age (years)	61·9	11·9	62	19	98
Number of Clinic Visits per Patient	5.5	2.5	5	3	11

* SD = Standard Deviation.

Table 3
Descriptive statistics for systolic and diastolic blood pressure stratified by categories.*

Systolic Blood Pressure					
	Mean (mmHg)	SD (mmHg)	Median (mmHg)	Minimum (mmHg)	Maximum (mmHg)
Overall	152·8	24·7	152	85	230
Female	153·0	24·6	152	86	225
Male	152·7	24·7	150	85	230
18–39 years	138·4	22·5	141	100	183
40–64 years	150·6	25·0	150	85	225
≥ 65 years	156·7	23·6	155	90	230

Diastolic Blood Pressure					
Variable	Mean (mmHg)	SD (mmHg)	Median (mmHg)	Minimum (mmHg)	Maximum (mmHg)
Overall	93·3	15·2	91	36	186
Female	93·2	15·5	91	36	186
Male	93·4	14·7	91	57	155
18–39 years	93·8	18·2	95	54	130
40–64 years	94·2	15·5	91	50	186
≥ 65 years	92·0	14·6	90	36	159

* SD = Standard Deviation.

3.5. Patient characteristics and clinician adherence to protocol

Only 41·9% (n = 1022 visits) of patients who received antihypertensive agents came to two consecutive clinics. Patient adherence to antihypertensive treatment was not measured for this study. A wide variation in protocol adherence was observed at the different clinic stations (Table 4). Protocol adherence for the first BP check at the Triage Station was 100% (n = 4601 visits) for patients who were ≥ 40 years of age, pregnant, or had previously received antihypertensive medication. Adherence for the second BP check at the Medical Station was 33·2% (n = 2937 visits) overall, 33·5% (n = 2862 visits) for patients ≥40 years of age with hypertension, and 18·7% (n = 75 visits) for pregnant patients. Protocol adherence to medication dispensing at the Pharmacy Station when medications were ordered was 82.8% (n = 1309 visits). Of these patients who received antihypertensive medication, 44·6% had a history of receiving medications from the outreach clinics and 55·4% were newly diagnosed patients with hypertension.

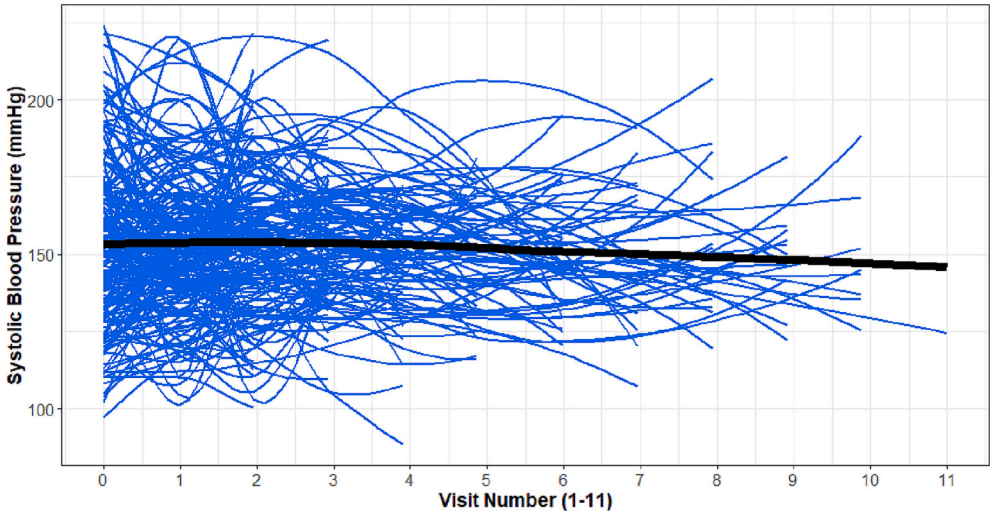

Fig. 1. Smooth nonparametric trajectories for SBP.

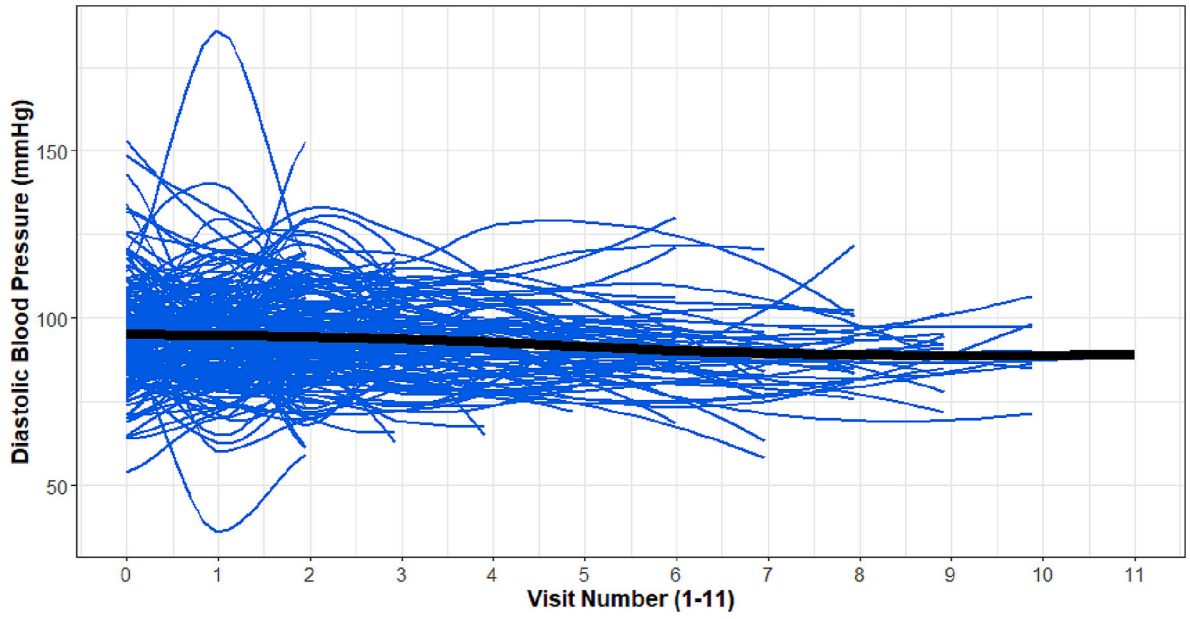

Fig. 2. Smooth nonparametric trajectories for DBP.

Table 4
Clinician adherence to clinic protocol.

	n (visits)	%
Adherence for the first blood pressure check at the Triage Station	4601	100
Adherence for the second blood pressure check at the Medical Station	2937	33·2
Patients ≥40 years of age with hypertension	2862	33·5
Pregnant patients with hypertension	75	18·7
Adherence for medication dispensing at the Pharmacy Station	1309	82·8
New diagnosis of severe hypertension	1084	55·4
Patients who had a history of receiving antihypertensive medications	1084	44·6

4. Discussion

The hypertension management during biannual outreach clinics did not significantly reduce the BP of Haitians with severe hypertension residing in the remote rural community. While there was a statistically significant decrease in DBP of 0·70 mmHg in the multilevel models, the clinical significance of that decrease is minimal because most manual sphygmomanometers are not sensitive enough to detect small BP changes [26,27]. Since hypertension and hypertensive disorders in pregnancy are modifiable risk factors for atherosclerotic diseases such as myocardial infarctions, strokes, and coronary artery disease, effective antihypertensive treatments are vital to reduce morbidity and mortality [1,8,10,28]. In the Medical Station, protocol adherence was low, with only 33·2% of indicated individuals receiving a second BP check. Antihypertensive medications were given to 82·8% of indicated patients with severe hypertension. Only 42% of patients who received antihypertensive medications came to two consecutive clinics. These suggests that many patients did not receive consistent treatment or regular follow-up through outreach clinics. These findings are consistent with prior studies showing that BP control and treatment is a significant challenge in hard-to-reach populations in rural Haiti [5,29]. This is especially true regarding hypertensive disorders in pregnant women in Haiti, to include preeclampsia, eclampsia, and postpartum hypertensive disorders [30,31].

In a study of patients who received antihypertensive treatment during a one-week long outreach clinic held in Léon [29], an area of eastern Haiti, medical providers dispensed medications from the following drug classes: calcium channel blockers (CCB), angiotensin-converting enzyme inhibitors (ACEi), diuretics, and beta-blockers. Hypertension prevalence in patients 50 years or older in the Léon clinic [29] was 45%, similar to that in the Timo clinic population [29]. Metz et al. examined the effectiveness of different antihypertensive agents in the Haitian population [5]. The most common classes of agents used in the study included CCB, thiazide diuretics, ACEi, beta-blockers, and angiotensin II receptor blockers. The median BP for participants taking antihypertensive medications was 150/88 mmHg (IQR SBP 134–164 mmHg, DBP 78–99 mmHg), implying that BP control was not achieved in their population [5]. This finding is similar to the median BP (152/91 mmHg) in our outreach clinic in Timo. These two studies confirm our findings that hypertension is highly prevalent in Haiti and difficult to control in Haitian populations, especially through short outreach clinics.

Clinic structures and protocol factors are possible explanations for the lack of significant reductions in BP [22]. Although biannual outreach clinics made antihypertensive treatment accessible and convenient, they were not originally structured to provide consistent follow-up care and monitoring for patients with chronic conditions like hypertension. Additionally, volunteer providers who participated in multiple clinics were more familiar with the hypertension protocol than first-time volunteers and more likely to follow the protocol. Over the study period, patients typically remained on a single medication with no dose adjustments. Our study showed that biannual follow-up and treatment with amlodipine or labetalol monotherapy were insufficient to achieve adequate BP control in our population. A study in Black barbershops in the United States showed that BP lowering in hard-to-reach populations is most effective when consistent follow-up with medical providers, monitoring, and health education are provided and easily accessed in community settings [32]. In remote areas, patients with hypertension and other chronic diseases might benefit from frequent outreach clinics staffed by local providers, clinicians, and CHWs. Carefully designed regular outreach would make returning to clinic easier for patients; and local staffing of those clinics might provide culturally congruent follow-up care that includes BP measurements, referrals to a higher level of care, and combination drug therapy.

Patient factors likely influenced the BP outcomes in this study. The trajectories for SBP and DBP measurements (Figs. 1 and 2) show much within-person variability. This fluctuation raises questions about individual adherence to drug therapy. Periods of controlled BP might reflect good adherence to drug therapy, while inconsistent medication adherence might not yield any benefits. Therefore, during follow-up visits, clinicians should routinely inquire about patient medication adherence, side effects, barriers, and facilitators. Additionally, researchers should assess patient knowledge and perceptions about therapy to better determine how BP outcomes correlate with patient variables.

Outreach clinic protocols designed to manage chronic conditions could adopt a patient-centered and sustainable approach with the following four-item checklist. First, clinicians should measure and promote adherence to treatment. This will help the clinician assess the appropriateness of changing medications or adding a second medication. Second, clinicians should provide patients with education and lifestyle changes before adding a second-line agent. Patients can help lower their BP by changing health behaviors, such as through diet and exercise [7,19]. In terms of hypertension management, many citizens in rural areas in Haiti already grow many of the foods recommended in the DASH diet and usually meet the exercise recommendations during their day-to-day activities [19], but this should not be assumed true for every patient. This step could promote healthy choices among local resources, including reducing sodium intake [7,9,33]. Third, laboratory testing might be introduced during follow-up appointments with local providers capable of providing culturally congruent care. The basic metabolic panel (BMP) can monitor patient electrolytes and help to determine whether the kidneys could withstand the addition of a second-line antihypertensive agent [34]. Finally, after completing the previous items, a second-line agent that is locally available and affordable might be safely considered for patients with persistent elevated BP values or refractory hypertension. Providing safe and effective disease management is extremely important, especially for populations with limited access to healthcare and emergency services.

There are both limitations and strengths to this study. First, due to the nature of chart reviews, information was limited about antecedents and social determinants of health, such as cultural, environmental, and personal factors that might affect BP management. The design did not allow for measurement of patient adherence to prescribed medications - even though medications may have been dispensed, that does not necessarily mean they were taken, or taken correctly. A lack of adherence to antihypertensive treatment could cause the study results to show no change. BP values could even be affected if patients did not take antihypertensive medications on the day of the clinic. Second, information in patient charts was collected for purposes of clinical practice documentation, not for the intent of completing research. As a result, some information was missing or incomplete. The low literacy in the community and indecipherable handwriting on paper charts, likely contributed to data errors. Data collection errors such as look-alike sound-alike words and numbers, language barrier, keyboard errors, and missing information due to verbal orders also likely contributed to data errors. Another potential limitation is that providers could not complete two BP checks on two consecutive days as recommended by the World Health Organization when diagnosing hypertension [1]. This limitation is due to outreach clinics logistics and patients' geographic residence. Since patients often walked several hours to attend clinics, BP readings could be elevated due to physical activity. Additionally, asking patients to return two days in a row would be impractical. As a result, two BP measurements were completed on the same day at two different clinic stations to diagnose hypertension and treat patients with severe hypertension.

5. Conclusion

This study suggests that simply dispensing medications for hypertension and other chronic conditions is not likely to be sufficient, among hard-to-reach populations with limited healthcare access and resources. Chronic conditions require comprehensive outreach efforts. Despite the level of physical activity inherent to living in rural and mountainous areas and easy access to fresh produce, hypertension prevalence among residents in rural Timo 40 years and older or pregnant women was similar to the hypertension prevalence in other rural areas of Haiti and nearly twice that in the Americas [2–5]. Although HHI outreach clinics made antihypertensive treatment accessible to this vulnerable population, efforts to date have had little impact on reducing severe hypertension. We suspect this is because of a lack of (1) access to regular follow-up care, (2) adjustment of prescription medication, and (3) return to clinic for treatment; all problems inherent to the ephemeral nature of outreach clinics. Future studies should examine the interplay of factors that affect blood pressure control in this community and identify those that are modifiable. In the short term, outreach clinics could be established to inquire about patient adherence to antihypertensive medications, encourage lifestyle changes, consider laboratory testing, and potentially facilitate the safe addition of a culturally appropriate and affordable second-line medication.

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Declaration of Competing Interest

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