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Improved blood pressure control via a novel chronic disease management model of care in sub-Saharan Africa: Real-world program implementation results

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Abstract

A chronic disease management model of care (Empower Health) was launched in rural and urban areas of Ghana and Kenya in 2018. The goal was to improve disease awareness, reduce the burden of disease, and improve the clinical effectiveness and efficiency of managing hypertension. Leveraging the model, clinicians provide patients with tailored management plans. Patients accessed regular blood pressure checks at home, at the clinic, or at community-partner locations where they received real-time feedback. On the mobile application, clinicians viewed patient data, provided direct patient feedback, and wrote electronic prescriptions accessible through participating pharmacies. To date, 1266 patients had been enrolled in the "real-world" implementation cohort and followed for an average of 351 ± 133 days across 5 facilities. Average baseline systolic blood pressure (SBP) was 145 ± 21 mmHg in the overall cohort and 159 ± 16 mmHg in the subgroup with uncontrolled hypertension (n = 743) as defined by baseline SBP ≥ 140 mmHg. SBP decreased significantly through 12 months in both the overall cohort (−9.4 mmHg, p < .001) and in the uncontrolled subgroup (−17.6 mmHg, p < .001). The proportion patients with controlled pressure increased from 46% at baseline to 77% at 12 months (p < .001). In summary, a new chronic disease management model of care improved and sustained blood pressure control to 12 months, especially in those with elevated blood pressure at enrollment.

1 | INTRODUCTION

Uncontrolled hypertension remains the primary reversible contributor to cardiovascular morbidity and mortality leading to stroke, heart failure, kidney disease, and hypertensive crisis.[1] The proportion of death and disability-adjusted life-years attributed to uncontrolled hypertension rose by an estimated 107% from 1990 to 2015 in West Africa.[2,3] In Ghana and Kenya, nearly 30% of the population has hypertension, but less than 5% of those with hypertension are adequately controlled.[3,4] This catastrophic state is due in part to multiple socioeconomic barriers including limited access to care, inefficient linkages between diagnosis and treatment, poorly accessible patient health records, referral delays and lack of patient awareness, and education.[5] Indeed, a recent cross-sectional survey in urban clinics of twelve sub-Saharan African countries specifically emphasized economic barriers

associated with lower hypertension control rates in the lowest income subgroup.[6]

In order to directly address these challenges, a novel, locally appropriate chronic disease management model of care was developed using human-centered design methodology[7] (Empower Health). The model employs five critical elements (Figure 1) including community-based screening, personalized follow-up plans, community-based health checks, data tracking and provider notifications, and electronic prescriptions. Following completion of a separate, successful 6-month pilot study,[8] the model was implemented in 2018 in Ghana and Kenya. The goal of the present analysis was to quantify changes in blood pressure (BP) over time following local implementation of the program.

2 | METHODS

The real-world implementation phase of Empower Health commenced following completion and analysis of the pilot phase. The model was initiated with employers, clinics, and community hospitals which provided ethical oversight and in-person and longitudinal health services through their health care organizations in conjunction with the Medtronic Labs Empower Health team, as specified by formal service agreements. The Empower Health management service was offered by the private employer or clinic to employees and patient clients. Therefore, all patients included were already engaged in an organized health care system and all had previously been screened for hypertension. Individuals over the age of 18 with a diagnosis of hypertension, regardless of current medication use, were eligible for enrollment. Patients continued to utilize usual personal payment mechanisms for in-clinic medical reviews and medications (ie, national health insurance, private insurance, or out of pocket payments). All patients consented in writing to program participation as well as provision of deidentified data for analysis and publication.

2.1 | Enrollment and follow-up plan generation

Baseline blood pressure was recorded for each patient at enrollment as the average of 3 consecutive measurements at rest at least 1 minute apart (Omron). Demographic and medical history data, and baseline BP were manually entered into the software application. The application then automatically generated an individual follow-up plan based on international guidelines[9,10] and enabled clinical risk categorization of patients based on comorbidities and risk factors. The follow-up plan was customizable at the health care provider's discretion for frequency of BP check assessments and in-person medical reviews. Patients received training on the Empower Health program from the participating health care provider that included the individualized risk-based follow-up plan and information on community-based BP check means.

2.2 | Community-based BP measurements

As part of the Individual Follow-up Plans, each patient was asked to attend weekly, bi-weekly or monthly in-person blood pressure assessments, as determined by the application or as customized by their providers. Automated BP assessments were primarily performed by trained personnel while the patient visited a local community location (eg, pharmacy) or at a central employment location. In a minority of cases, and depending on the local facility's protocols, existing local community health workers acquired the blood pressure measurements directly in the patients' home. Patients were not provided with home blood pressure monitors or any other technology and home monitoring was not required. However, if the patient was literate and had access to a personal smartphone and an automated home BP machine, then they could also monitor their BP at home, but these measurements were not recorded in the system. During the BP assessment interactions, patients also self-reported current and recent physical symptoms

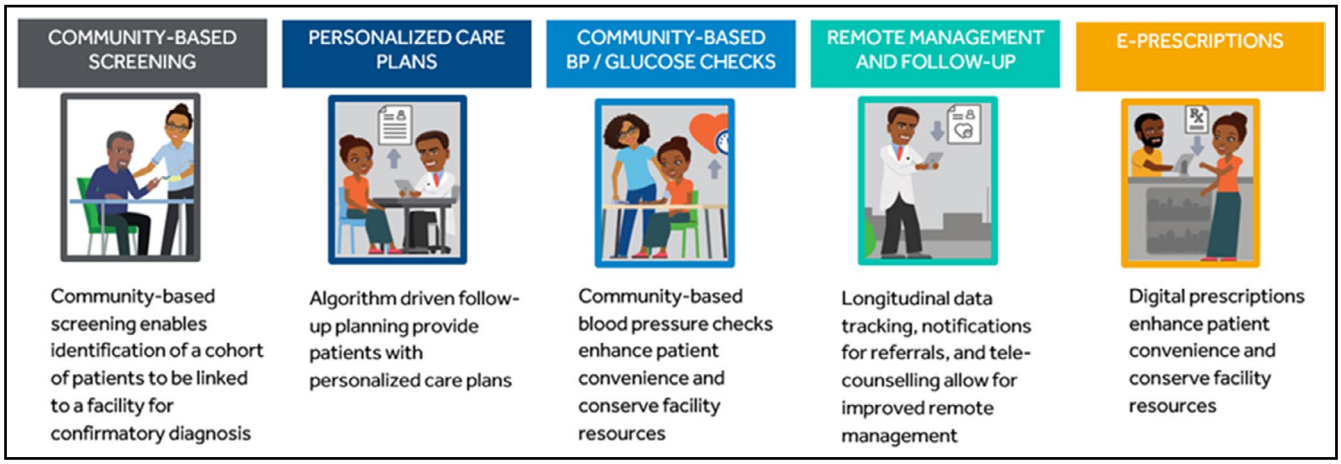

FIGURE 1 Hypertension management model of care: The locally appropriate model of care was developed using human-centered design methodology and included community-based screening, personalized care plans, community-based blood pressure monitoring, remote management, and follow-up and electronic prescription generation

TABLE 1 Baseline population demographics

Patient characteristics	Total subjects (*N* = 1266)	Uncontrolled (*N* = 743)	Controlled (*N* = 523)	*p*-Value[a]
Age (years)	58 ± 13	57 ± 13	59 ± 13	.007
Gender (*N*,% Female)	760 (60%)	408 (55%)	352 (67%)	<.001
BMI (kg/m^2)	27 ± 6	27 ± 7	27 ± 5	.403
Uncontrolled BP, SBP ≥ 140 mmHg (*N*,%)	743 (59%)	743 (100%)	0 (0%)	1.00
Baseline SBP (mmHg)				
Mean ± Standard deviation	145 ± 21	159 ± 16	126 ± 10	<.001
Median	144	154	128	
25th Percentile-75th Percentile	130-157	146-166	120-134	
Minimum-Maximum	87-255	140-255	87-139	
Baseline DBP (mmHg)				
Mean ± Standard deviation	89 ± 13	95 ± 12	81 ± 9	<.001
Median	89	94	80	
25th Percentile-75th Percentile	80-97	88-101	75-86	
Minimum-Maximum	50-143	59-143	50-103	
Heart rate (bpm)	79 ± 14	79 ± 14	78 ± 14	.120
Diabetes (*N*, %)	240 (19%)	130 (17%)	110 (21%)	.099
Arthritis (*N*, %)	18 (1%)	8 (1%)	10 (2%)	.235
Heart failure (*N*, %)	20 (2%)	10 (1%)	10 (2%)	.495
History of coronary heart disease (*N*, %)	181 (14%)	86 (12%)	95 (18%)	.001
History of stroke or Tia (*N*, %)	24 (2%)	14 (2%)	10 (2%)	1.00
Peptic ulcer disease (*N*, %)	23 (2%)	10 (1%)	13 (2%)	.141
Baseline hypertension medications[b]				
Average number of HTN meds per patient	1.7 ± 0.9	1.8 ± 0.9	1.5 ± 0.9	<.001
Not on medication	14%	12%	17%	
On 1 HTN medications	19%	17%	24%	
On 2 or more HTN medications	55%	56%	52%	
On 3 or more HTN medications	12%	15%	6%	
Baseline medication by class (% of patients)				
ACE	25%	22%	32%	.004
ARB	38%	45%	27%	<.001
ACE or ARB	64%	66%	58%	.053
Aldosterone antagonist	0.1%	0.2%	0%	1.00
Beta-blocker	10%	10%	11%	.593
Calcium channel blocker	74%	77%	67%	.003
Central acting agents	5%	7%	1%	<.001
Diuretic	14%	16%	11%	.109
Vasodilator	0.1%	0.2%	0%	1.00

[a]*p*-Value calculated by *t*-test for continuous variables and exact test for dichotomous variables, comparing uncontrolled subgroup versus controlled subgroup baseline characteristics.

[b]672 patients reported baseline medication data.

and hypertension medication adherence. Three automated blood pressure measurements were then performed by the community provider on the seated patient according to guideline methods[11] and recorded electronically into the application. A one-minute waiting period was observed between each BP measurement during which time the patient could watch application-based educational messages pertaining to the risks of high BP, the importance of medication adherence, and locally appropriate healthy lifestyle messaging. Based on the patient's enrollment risk classification and their reported symptoms and blood pressure from that day, the patient received an application-generated personalized message. Depending on the patient's literacy level, the message

was either read by the patient or delivered verbally by the health care worker. The patient message included actionable information including positive verbal feedback, prompts to repeat blood pressure readings within a few days, or instructions to proceed immediately to the clinic or hospital for additional medical evaluation.

2.3 | Data triaging and health care provider notifications

When a patient received a message to seek additional medical evaluation (referral) following a community-based BP check, the physician (or Health Care Provider [HCP] assigned to receive the alerts) received an SMS message indicating that the patient had been referred. The application was also available to the physician at any time, including during in-person visits, to review the patient's longitudinal blood pressure measurements and follow-up with patients who had missed BP checks or medical reviews. The physician could also directly call or send an SMS message via the application to patients communicating patient-specific follow-up instructions.

2.4 | Electronic prescriptions

The software application provided a paperless mechanism for the physician to write hypertension-related prescriptions, selecting from hypertension-related medications available for use within the specific country. Patients were then informed by SMS via the application that their prescription was available to be picked up at the participating pharmacy.

Commercially available Omron BP monitors were used for all blood pressure measurements, and the Empower Health software application was deployed on computer tablets provided by the program (Samsung Galaxy™) and purchased by the participating facilities. The physicians received the application-generated patient notifications via their personal smartphones. In-clinic medical review visits were conducted over the 12-month duration of the follow-up either every 30, 60, or 90 days. The frequency of these in-clinic medical reviews was determined by the risk classification performed by the Empower Health system algorithm at enrollment and confirmed or modified by the physician as clinically indicated. During those in-clinic medical reviews, the patient's provider had access to the longitudinal data collected during the community-based BP assessments. The provider could also update the BP assessment or in-clinic visit frequencies and/or update and prescribe hypertension-related medications via the application.

2.5 | Statistical analysis

Pilot phase methods were previously reported.[8] In brief, the study was powered at >80% to test for a reduction in systolic blood pressure (SBP) of 5 mmHg through a 6-month follow-up period. For the real-world implementation phase, all patients were followed until voluntarily exiting the program. All enrolled subjects were included in analyses regardless of follow-up duration, and appropriate statistical methods were utilized to adjust for varying follow-up duration. At the time of analysis, a total of 1266 active patients had enrolled and had accrued follow-up ranging from 5 days to 1.4 years. To account for varying number of blood pressure checks per patient over varying follow-up periods, repeated measures regression analyses were completed. For analysis, the final two of three BP readings were averaged. Subjects were defined as uncontrolled if the average of baseline SBP measurements were greater than or equal to 140 mmHg (SBP ≥ 140 mmHg). A piecewise linear mixed model was utilized to estimate the reduction in blood pressure during follow-up with a first order autoregressive covariance structure utilized to account for correlation between repeated blood pressure measurements within a subject. Selection of knot was estimated using local polynomial regression (LOESS) analysis. Estimates of change in blood pressure through 12-month were calculated from the regression model. Similarly, the increase in proportion of subjects with controlled hypertension (SBP < 140 mmHg) over the course of follow-up was estimated with a generalized estimating equation to account for repeated BP checks within a patient. Similar methods were utilized to assess the change in diastolic blood pressure over follow-up. The association between more frequent blood pressure checks and reduction in blood pressure was assessed with a regression model; change in blood pressure was the dependent variable, number of blood pressure checks, and baseline blood pressure were the covariates. SAS Software Versions 9.4 (SAS Institute, Cary, North Carolina) was used to conduct data processing and statistical analysis.

3 | RESULTS

3.1 | Patient characteristics

After completion of the pilot study, patient recruitment in the program began in February 2018 and 1266 patients had been enrolled as of July 2019 across 9 facilities in Ghana and Kenya, with average follow-up time in the program of 351 ± 133 days [range: 5-522 days]. These facilities include five private centers/ clinics, two employers, and two community hospitals. Average age was 58 ± 13 years; 60% of patients enrolled were female. The average baseline blood pressure was 145 ± 21/89 ± 13 mmHg. The enrolled cohort included 59% (743/1266) with uncontrolled hypertension according to baseline measurements, with average blood pressure of 159 ± 16/95 ± 12 mmHg. Based on the baseline clinical assessment most patients (n = 722, [57%]) were assigned bi-weekly follow-up while 42% (n = 535) were assigned weekly follow-up and the remainder (<1%) were assigned monthly or daily follow-up. Average baseline blood pressure in the controlled cohort was 126 ± 10/81 ± 9 mmHg. Patients were prescribed an average of 1.7 ± 0.9 hypertensive medications at baseline, including

74% on calcium channel blocker, 64% on ACE or ARB, and 14% on diuretic (Table 1). Patients in the uncontrolled subgroup were slightly younger (57 ± 13 versus 59 ± 13 years, $p < .007$), fewer females (55% versus 67%, $p < .001$), and more were prescribed antihypertension medications (1.8 ± 0.9 versus 1.5 ± 0.9 hypertension medications per patient, $p < .001$). (Table 1).

Of the 5538 BP assessments carried out over the 12-month period, 89% were completed by a community health workers and trained BP checkers, 7% were completed by a nurse, and the remaining 4% were completed by clinicians. Patients reported they were taking all blood pressure medications as prescribed at 96% of blood pressure checks. Throughout the 12 months, 5604 SMS messages were sent to the patients, directly from their physicians, through the software application. Of these SMS messages, 32% provided direct feedback following a review of a patient's BP/symptoms data and 68% were sent to notify the patient that a prescription had been written by their health care provider and was ready to be picked up at their participating pharmacy. Of the centers using the software's electronic prescription workflow to capture details on electronic prescriptions filled, a total of 67% of patients had a prescription filled during follow-up, with an average of 2.0 prescriptions filled per patient.

The software application algorithm logic directly referred 11% of the patients ($N = 146$) to a health facility following a community-based BP assessment, representing 4% of the total BP assessments completed.

3.2 | Regression analysis

A total of 5538 blood pressure checks were completed during the program with a median rate of 3 blood pressure checks per 12 months of follow-up (median 3, IQR: 2-8). Baseline blood pressure estimated by the regression model was 142.3 mmHg (95% CI: 141.3-143.3), which was similar to the raw absolute blood pressure (145 ± 21 mmHg). A significant systolic blood pressure (SBP) reduction of −9.4 mmHg was estimated over 12 months of follow-up with reductions of −6.7 mmHg (SBP 135.6, 95% CI: 134.6-136.6) at 3 months, −9.0 mmHg (SBP 133.3, 95% CI: 132.3-134.3) at 6 months, and continued sustained reduction at 12 months (reduction of −9.4 mmHg, SBP = 132.9, 95% CI: 131.7-134.1), [$p < .001$, Figure 2]. A significantly greater rate of BP reduction was observed in the subgroup with uncontrolled versus controlled BP at baseline (between group interaction $p < .001$; Figure 3). In the subgroup with uncontrolled hypertension ($n = 743$), a significant reduction in SBP of −17.6 mmHg over 12 months was observed (baseline 154.1 mmHg (95% CI: 152.9-155.3) to 136.5 mmHg (95%: 135.0-138.0) at 12 months, $p < .001$). Blood pressure in the subgroup with controlled pressure at baseline ($n = 443$; 125.8 mmHg [95% CI: 124.6-126.9]) remained controlled at 12 months (128.2 mmHg [95% CI: 126.9-129.5]).

The reduction in overall blood pressure was associated with an increase in the proportion of patients with "controlled" blood pressure readings during follow-up (SBP < 140 mmHg). Of the 1266 patients, only 523 (41%) had controlled blood pressure at baseline. Regression analysis indicated the proportion of blood pressure measurements with controlled pressure increased from 46% at baseline to 77% at 12 months ($p < .001$, Figure 4). Again, the regression model estimated similar baseline BP with an increase of 31% of subjects with controlled blood pressure at 12 months.

Similar reductions were observed for diastolic blood pressure measurements. Average diastolic blood pressure reduction at 12 months was −5.5 mmHg (95% CI: −6.5, −4.6) in the full cohort, −10.2 mmHg (−11.5, −9.0) in the uncontrolled subgroup, and 0.9 mmHg (−0.4, 2.2) in the baseline-controlled group (Figure 3). Blood pressure reduction was observed across all subgroups. No difference in blood pressure reduction was observed according to sex, age, diabetes, BMI, or country (Table 2).

More frequent blood pressure checks were associated with a greater reduction in blood pressure. Regression analysis estimated that each additional BP check per month corresponded to −4.0 mmHg (95% CI: −6.1, −1.8, $p < .001$) additional drop in SBP through 12 months. In contrast, baseline blood pressure was not associated with more or less frequent return for blood pressure checks ($p = .70$).

4 | DISCUSSION

This prospective real-world investigation demonstrated the utility of a novel, co-created, locally appropriate model of care implemented to address formidable socioeconomic barriers to blood pressure control for individuals living with hypertension in rural and urban areas of Ghana and Kenya. The program resulted in clinically and statistically significant systolic and diastolic blood pressure reduction across the entire cohort that were sustained out to 12 months (Figures 3-4). Importantly, subgroup analysis indicated that this reduction occurred primarily in patients with uncontrolled BP at enrollment (Figures 2-3). The drops in blood pressure plateaued at about 4 months and were sustained over the entire 12-month follow-up period. Additional analysis indicated that blood pressure drops were similar for subgroups based on sex, age, geography, and BMI. The presently observed drops in blood pressure have the potential to make meaningful long-term clinical impact, since similar drops have been associated with large reductions in cardiovascular risk, including coronary heart disease events (by about 25%), stroke (by about 41%), and heart failure (by about 25%).[12]

The present results extend the findings of the prospective pilot investigation of 150 patients with hypertension showing similar patterns of blood pressure reduction over 6 months.[8] Systolic blood pressure decreased significantly after 6 months of recommended weekly BP monitoring in both the overall cohort (−4.7 ± 18.7 mmHg, $p < .01$). The proportion of the population with uncontrolled hypertension decreased from 39% to 27% ($p = .01$). In-clinic patient visits were reduced 60% as compared to standard monthly visits. Notably, that trial also included a retrospective analysis of patients' routine

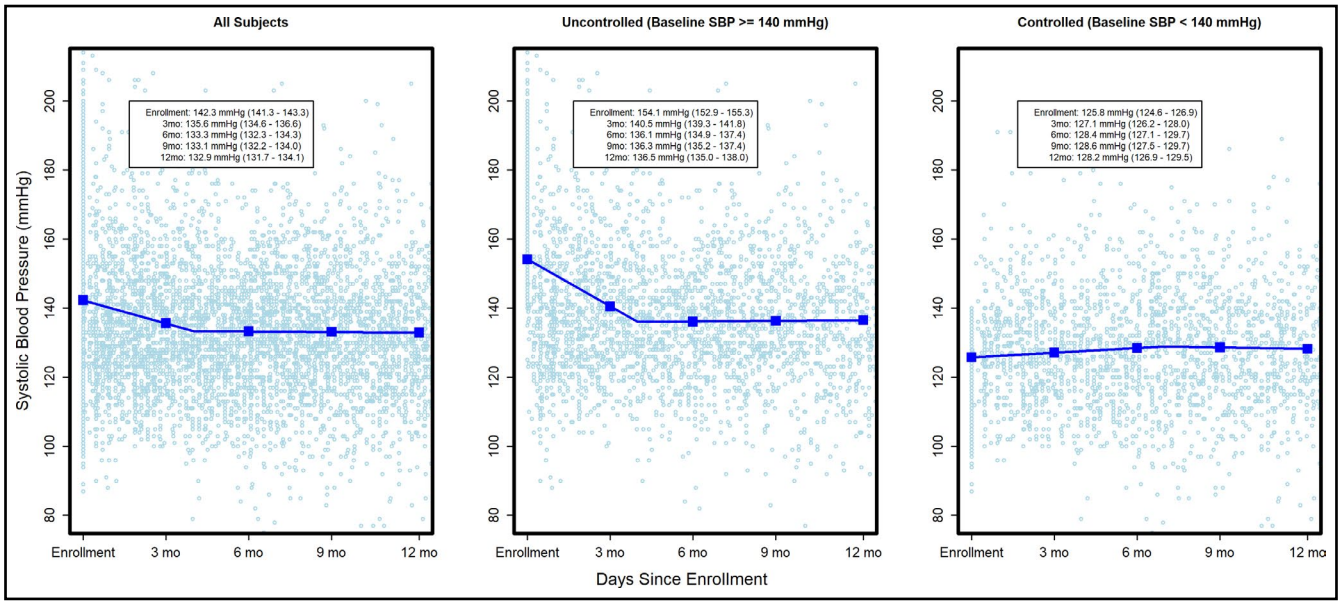

FIGURE 2 Systolic blood pressure at enrollment, 3, 6, 9, and 12 months following enrollment in Empower Health for all patients. Reduction in blood pressure was estimated via a piecewise linear mixed model and was significantly reduced over 12 months in the full cohort and in the subgroup with uncontrolled BP at baseline ($p < .001$). Selection of knot was determined by LOESS analysis with knots at day 120 for the full cohort and uncontrolled subgroup, and day 210 for the controlled subgroup

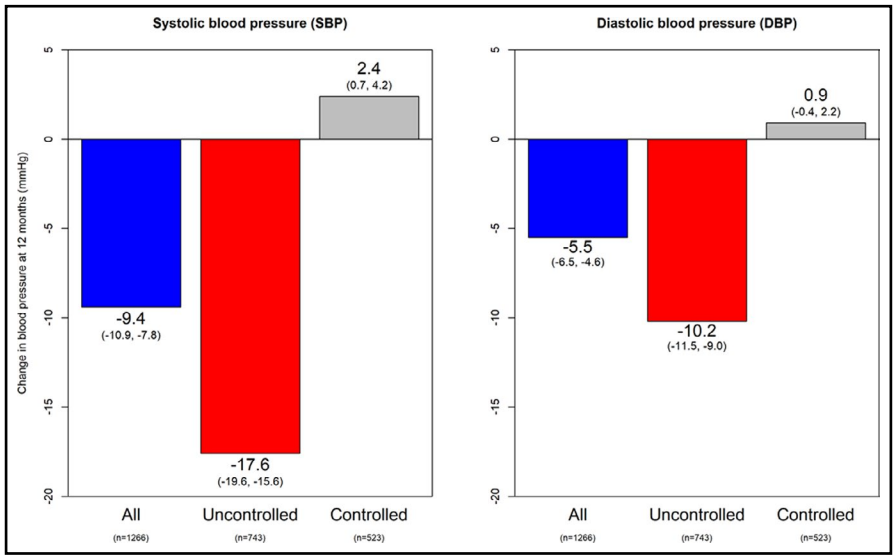

FIGURE 3 Changes in blood pressure following enrollment in Empower Health at 12 months follow up period for all patients enrolled (blue), uncontrolled hypertension (red), and controlled hypertension (gray). Data are mean (95% CI)

office blood pressure records showing no change in blood pressure within the population during the 6 months prior to enrollment.

Recently, results were reported from the Optimizing Linkage and Retention to Hypertension Care in Rural Kenya (LARK) initiative that applied smartphone technology and community health worker interaction to improve linkages between uncontrolled hypertensive patients and the health care system.[13] The randomized study showed that the model led to improved linkage to care but did not lead to improvement in BP reduction as compared to "usual care" and the authors concluded that further innovations are needed. Despite similarities in strategy around establishing patient linkage, the Empower Health System model differs from LARK and other systems[14,15] in several important ways including ongoing data analysis of BP readings linked to triaging, physician alert notifications, application-based educational information, personalized SMS messaging to patients, and electronic prescription capabilities. Also, existing models are not designed to address socioeconomic care barriers including maintaining patient engagement and support, time and cost burden of traveling to the clinic, lack of patient awareness to the current state of their condition, and longitudinal triaged data to inform clinical care decisions.

Our findings during the implementation of this program have important implications for the hypertensive population beyond Ghana and Kenya. Hypertension remains a growing epidemic in Africa where the population is expected to exceed 2.4 billion by the year 2050.[16] Estimates of the prevalence of hypertension in Africa

are among the world's highest at up to 46%. Conversely, hypertension control rates in Africa are among the world's lowest at 6.5%, explained in part by low hypertension awareness levels of just 34%.[17,18] Such low control rates indicate the opportunity and value of expanding the Empower Health program going forward.

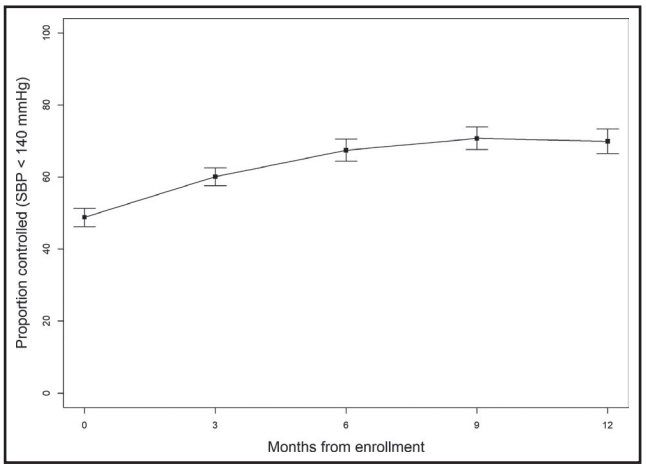

FIGURE 4 Proportion of population with systolic blood pressure controlled below 140 mmHg at 3, 6, 9, and 12 months: Based on regression modeling, the proportion of subjects with controlled hypertension increased from 48.8% at baseline to 69.9% at 12 months ($p < .001$)

Our analysis has important limitations. The current real-world cohort may not represent the broader sub-population of undiagnosed or untreated patients outside an organized health care system. The analysis did not include a control arm for comparison. However, gradual, consistent, and sustained decreases in blood pressure were demonstrated in a population with previously well-documented poor rates of hypertension control. Furthermore, the gradual decrease in pressure for the population as well as the lack of pressure changes in the subgroup with controlled blood pressure at baseline suggest that our observations are probably not indicative of regression to the mean. Additionally, without a control arm, the reduction in blood pressure could be related to the Hawthorne effect, that is the frequency and awareness of being observed. However, the magnitude of the blood pressure reduction and the sustainment of the large reduction through a year of follow-up provides evidence against only a Hawthorne effect.

In summary, this model of community-based care, implemented across rural and urban facilities in Ghana and Kenya, addressed formidable barriers to hypertension management resulting in decreased blood pressure that was sustained over 6 months in a prospective pilot phase and over 12 months in the subsequent program implementation phase. Future study is planned to address program effectiveness within different facility types and to quantify the short-term and long-term cost savings and financial benefits to the patients, country workforce, and to health systems at large.

TABLE 2 Changes in systolic blood pressure by sub-group

	N	Baseline (95% CI)	Month 12 (95% CI)	Difference (95% CI)	*p*-Value[a]
Sex					
Male	506	144.3 (142.9, 145.8)	133.8 (131.7, 135.8)	−10.6 (−13.1, −8.1)	.739
Female	760	138.5 (137.3, 139.6)	130.4 (129.0, 131.8)	−8.1 (−9.9, −6.3)	
Diabetes[b]					
Yes	241	139.1 (137.1, 141.2)	131.6 (129.1, 134.1)	−7.5 (−10.8, −4.3)	.231
No	997	141.1 (140.1, 142.2)	131.5 (130.2, 132.8)	−9.7 (−11.3, −8.0)	
Age (years)					
≤40	118	142.3 (139.2, 145.4)	124.1 (118.9, 129.4)	−18.2 (−24.2, −12.1)	.110
41-50	251	141.8 (139.7, 143.9)	130.4 (127.6, 133.0)	−11.5 (−14.9, −8.1)	
51-60	368	140.3 (138.6, 142.0)	132.0 (129.9, 134.0)	−8.3 (−11.0, −5.6)	
61-70	309	140.1 (138.3, 141.9)	132.9 (130.8, 135.0)	−7.2 (−10.0, −4.4)	
>70	220	140.8 (138.6, 143.0)	131.4 (128.5, 134.3)	−9.36 (−13.0, −5.7)	
BMI (kg/m^2)					
≤20	73	136.9 (133.3, 140.6)	132.3 (128.3, 136.2)	−4.6 (−10.0, 0.8)	.543
21-25	385	140.7 (139.0, 142.3)	130.0 (128.1, 131.9)	−10.7 (−13.2, −8.1)	
26-30	476	142.1 (140.6, 143.6)	132.5 (130.3, 134.6)	−9.6 (−12.2, −7.0)	
>30	330	140.0 (138.2, 141.8)	132.3 (130.0, 134.5)	−7.8 (−10.7, −4.9)	
Country					
Ghana	638	141.4 (140.2, 142.6)	131.6 (130.4, 132.9)	−9.8 (−11.5, −8.0)	.609
Kenya	328	139.9 (138.5, 141.3)	130.7 (128.0, 133.3)	−9.2 (−12.2, −6.3)	

[a]Interaction test from linear mixed model.

[b]Diabetes status reported in 1238/1266 patients.

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CONFLICT OF INTEREST

FK, CL, DH are full time employees of Medtronic Inc; RS has received consulting and speaker fees from Medtronic; all other authors report no competing interests.

AUTHOR CONTRIBUTIONS

HAO and CM contributed to patient recruitment and the execution of the Empower Health Program. CL and MG designed and implemented the program. FK performed all statistical analysis. GY, RS and DAH provided program guidance and suggestions for analysis and data interpretation. HAO and DAH drafted the manuscript all authors contributed materially to the final document.

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