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Community Health Workers Improve Linkage to Hypertension Care in Western Kenya

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ABSTRACT

BACKGROUND Elevated blood pressure (BP) is the leading global risk factor for mortality. Delay in seeking hypertension care is associated with increased mortality.

OBJECTIVES This study investigated whether community health workers, equipped with behavioral communication strategies and smartphone technology, can increase linkage of individuals with elevated BP to a hypertension care program in western Kenya and significantly reduce BP.

METHODS The study was a cluster randomized trial with 3 arms: 1) usual care (standard training); 2) "paper-based" (tailored behavioral communication, using paper-based tools); and 3) "smartphone" (tailored behavioral communication, using smartphone technology). The co-primary outcomes were: 1) linkage to care; and 2) change in systolic BP (SBP). A covariate-adjusted mixed-effects model was used, adjusting for differential time to follow-up. Bootstrap and multiple imputation were used to handle missing data.

RESULTS A total of 1,460 individuals (58% women) were enrolled (491 usual care, 500 paper-based, 469 smartphone). Average baseline SBP was 159.4 mm Hg. Follow-up measures of linkage were available for 1,128 (77%) and BP for 1,106 (76%). Linkage to care was 49% overall, with significantly greater linkage in the usual care and smartphone arms of the trial. Average overall follow-up SBP was 149.9 mm Hg. Participants in the smartphone arm experienced a modestly greater reduction in SBP versus usual care (-13.1 mm Hg vs. -9.7 mm Hg), but this difference was not statistically significant. Mediation analysis revealed that linkage to care contributed to SBP change.

CONCLUSIONS A strategy combining tailored behavioral communication and mobile health (mHealth) for community health workers led to improved linkage to care, but not statistically significant improvement in SBP reduction. Further innovations to improve hypertension control are needed. (Optimizing Linkage and Retention to Hypertension Care in Rural Kenya [LARK]; NCT01844596) (J Am Coll Cardiol 2019; ■: ■ - ■) © 2019 by the American College of Cardiology Foundation.

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JACC VOL. ■, NO. ■, 2019

ABBREVIATIONS AND ACRONYMS

AMPATH = Academic Model
Providing Access to Healthcare
Partnership

AMRS = Academic Model
Providing Access to Healthcare
Partnership Medical Records
System

BP = blood pressure

CHW = community health

DBP = diastolic blood pressure
mHealth = mobile health

- modele meater

NPHW = nonphysician health worker

SBP = systolic blood pressure

ypertension, a major risk factor for ischemic heart disease, heart failure, and stroke (1), is the leading global risk for mortality (2). However, hypertension awareness, treatment, and control rates are low in Africa and worldwide (3). Given that hypertension may be asymptomatic, linkage and retention to care and medication adherence are particularly difficult challenges (4). Previous research in Kenya has indicated that linkage to hypertension care is very low, approximately 25% (5). Delays in seeking hypertension care have been shown to be associated with increased mortality (6). Thus, early linkage to hypertension care and successful retention to clinical services are critical components of hypertension management.

Recent studies have indicated that nonphysician health workers (NPHWs) can improve hypertension management and blood pressure (BP) control (7,8). In particular, community health workers (CHWs)—members of a community who have received basic training to supply community members access to health and social services, to educate individuals about various health issues, and to support overall community development (9)—have been shown to have a positive impact when they are integrated into hypertension management programs (10). However, the specific impact of CHWs on linkage to hypertension care in Africa is relatively unknown.

We report here the results of the LARK Hypertension Study (Optimizing Linkage and Retention to Hypertension Care in Rural Kenya; NCT01844596), which aimed to evaluate the impact of CHWs, equipped with behavioral communication strategies and mobile health (mHealth) technology, on linkage to hypertension care and BP reduction among individuals with elevated BP in western Kenya.

METHODS

SETTING. Full details of the study design and methods have previously been described (11). Briefly, the Academic Model Providing Access to Healthcare Partnership (AMPATH) was initiated in Kenya in 2001 and has established a care system for human immunodeficiency virus in western Kenya that has served more than 160,000 patients (12). On that foundation, and in partnership with the Government of Kenya, AMPATH expanded its clinical scope of work to include hypertension (13). This study was conducted within the AMPATH infrastructure in western Kenya, in Kosirai and Turbo Divisions. The protocol was

approved by the Institutional Review Boards of all participating institutions, and the study is registered on www.clinicaltrials.gov (identifier NCT01844596).

STUDY DESIGN. After an initial formative phase of qualitative inquiry (14), we used a participatory, iterative design process to develop the interventions, involving stakeholders representing clinicians, patients, CHWs, administrators, and informatics personnel. We conducted a cluster randomized trial with 3 arms: 1) usual care (CHWs with standard training); 2) "paper-based" (CHWs trained in tailored behavioral communication, using paper-based tools); and 3) "smartphone" (CHWs with tailored behavioral communication, using smartphone technology). The unit of randomization was a geographically and administratively unique community unit (population approximately 5,000), stratified by division, and there were 24 clusters total (8 per arm). Each community unit is geographically near a rural health facility associated with the AMPATH hypertension program. The randomization process was conducted centrally by biostatisticians at Brown University in Providence, Rhode Island. The participants and research staff were not blinded to intervention assignments. Study roll-out was conducted sequentially by arm: first the usual care community units, followed by paper-based and then smartphone intervention community units.

PARTICIPANTS AND **PROCEDURES.** Inclusion criteria for this study included adult individuals with elevated BP (systolic BP [SBP] ≥140 mm Hg or diastolic BP [DBP] ≥90 mm Hg) during community-based BP screening performed by trained research assistants, using a standard protocol with automated Omron BP machines (Omron, Kyoto, Japan) as described by WHO STEPS (15) and the Global Alliance for Chronic Diseases (16). Exclusion criteria consisted of individuals without elevated BP, those who were acutely ill and required immediate medical attention at the time of testing, and individuals who did not provide informed consent. Individuals actively engaged in hypertension care were excluded from the study. Individuals who met inclusion criteria and had no exclusion criteria were enrolled at the time of the community-based BP screening.

At the health facility, each individual had repeat BP measured by the clinician, and those with repeat elevated BP were entered into the hypertension management program as "patients." Patients were managed according to the AMPATH hypertension protocol derived from consensus guidelines for hypertension management, using drugs contained in the Kenyan national formulary (17–19) (Online Appendix).

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Once linked to care, patients were managed by a clinician (either a clinical officer or nurse) who had undergone hypertension care training and was equipped with the same care protocols. The clinicians had access to teleconsultation with a specialist whenever necessary.

An individual who did not present to the health facility within 1 month of BP testing was assigned to a CHW specific to the participant's community unit, who was requested to visit that person to encourage linkage to care. The CHW was equipped with the behavioral communication strategy with or without the mHealth tool, depending on the trial arm to which the CHW's community unit was randomly allocated.

In the usual care arm, the CHW referred the individual to the health facility for further evaluation and management, according to the usual AMPATH clinical care protocol. In the paper-based arm, the CHW was instructed to engage in behavioral, clinical, and environmental assessments, followed by a tailored behavioral and motivational engagement, to help facilitate linkage to care. In the smartphone arm, the CHW conducted the same assessments described earlier; however, the CHW was also equipped with a smartphone that had real-time decision support and data entry linked to the electronic health record. Thus, the smartphone provided tailored messaging and specific recommendations that were based on inputs from the assessments. The smartphone technology also allowed for alternative messaging modalities, including images, audio recordings, and video recordings (Online Appendix, Online Video 1). Follow-up assessment, including BP measurement, was conducted by trained research staff.

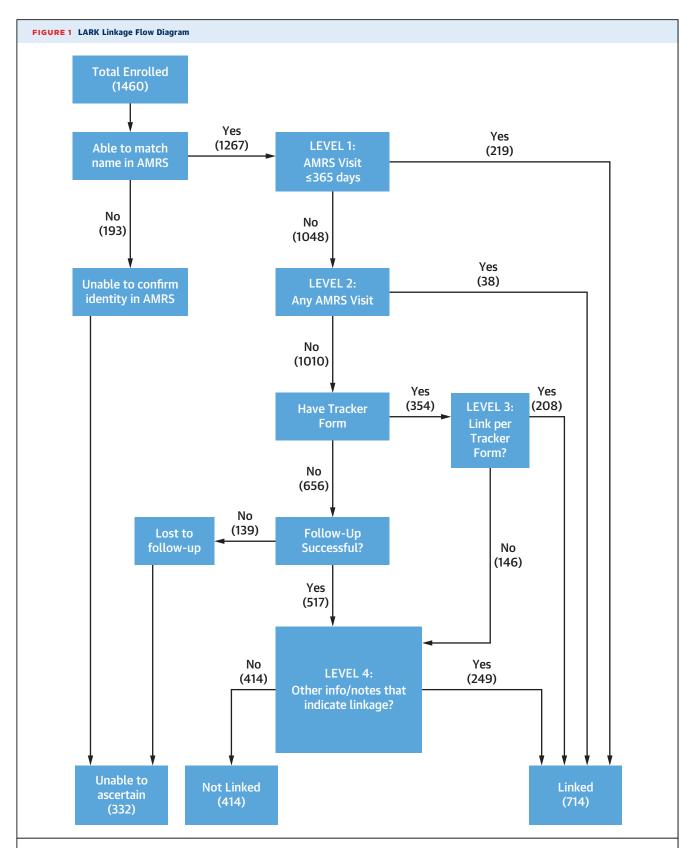
STATISTICAL ANALYSIS. The co-primary outcome measures were: 1) documented linkage to care; and 2) change in SBP. The study was powered on the linkage to care outcome. With 24 clusters across 3 trial arms, our power calculations demonstrated >80% power to detect a 20% difference in linkage, for a range of participants per cluster (down to an average of 50 per cluster).

The binomial linkage measure included either a visit at a health facility documented in the electronic medical record or a self-reported visit. Linkage to care was originally assessed by relying on data entered into the AMPATH Medical Records System (AMRS), an electronic medical record and clinical database, to confirm attendance at a clinic visit. However, this proved problematic for several reasons, including the following: 1) some individuals had multiple AMRS identification numbers, some of which did not match

the AMRS number recorded on the research data collection form; 2) some individuals had demographic data in the AMRS clinical data set that did not match demographic data collected by the research team, thus challenging verification of the individual's identity; and 3) some participants who actually linked to care did not have clinical information entered into the AMRS clinical database. In an attempt to mitigate these issues, a data collection form to record selfreported linkage to care was specifically created and administered to LARK participants at the research follow-up visit. Because the foregoing AMRS difficulties were detected after the trial had already started, not all participants were administered the "linkage tracker form." The research assistants kept notes about participants in their research logs, which were also used to determine linkage status if the tracker form was not available. We therefore constructed different categories of linkage depending on the nature and quality of data available for each participant (Figure 1).

Mixed-effects models were used throughout to evaluate the outcome measures, by using an intention-to-treat approach, taking into account geographic clustering. Bootstrap and multiple imputation were used to account for missing covariate and outcome data and to nest the primary outcomes and mediation analyses under 1 analytic umbrella. First, 6,000 bootstrapped samples of the data were generated, including missing values and using geographic community as the sampling unit (20). Next, multiple imputation was used to create 1 complete dataset from each bootstrapped sample (21). The main outcome analyses were adjusted for age, sex, enrollment SBP, and baseline covariates that were found to differ significantly across arms of the study: enrollment in national health insurance, tobacco and/or alcohol use, employment status, physical activity, awareness of hypertension status, and geographic division. Given the differential time to follow-up assessment across trial arms, the effects of the interventions on SBP were estimated at 15 months after enrollment, a time point common to all trial arms. We used a nonparametric spline for time to follow-up and allowed a linear interaction between trial arm and follow-up time. We averaged the estimates for the mean effect and constructed bootstrap 95th percentile confidence intervals, by removing the runs that did not converge. We also present a secondary analysis of the SBP outcome that was based on a partially adjusted model with only baseline SBP and follow-up time as covariates. All analyses were conducted using R software version 3.5.1 (R Foundation, Vienna, Austria).

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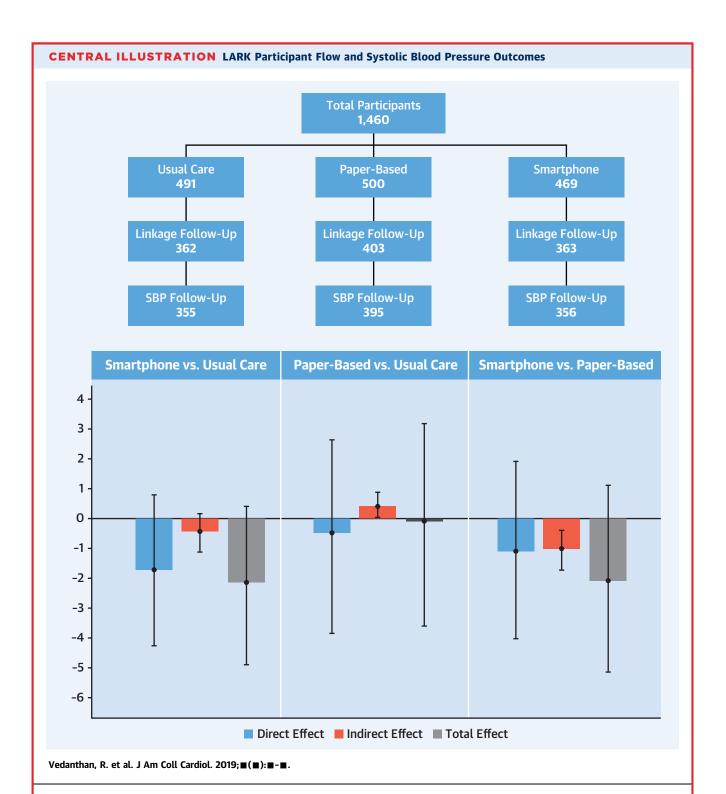


The different categories of linkage to hypertension care for participants in the study. AMRS = Academic Model Providing Access to Healthcare Partnership Medical Records System; LARK = Optimizing Linkage and Retention to Hypertension Care in Rural Kenya.

JACC VOL. ■, NO. ■, 2019

Vedanthan et al. Improving Linkage to Hypertension Care





The figure illustrates both participant flow through enrollment and follow-up, as well as the fully adjusted systolic blood pressure outcomes analysis including mediation. Vertical bars indicate 95% confidence intervals (Table 3). See Online Video 1. LARK = Optimizing Linkage and Retention to Hypertension Care in Rural Kenya.

	Total (N = 1,460)	Usual Care (n = 491)	Paper-Based (n = 500)	Smartphone (n = 469)
Participants per community unit, n	60.8 ± 14.2	61.3 ± 11.7	62.5 ± 9.6	58.6 ± 20.7
Age, yrs	54.2 ± 16.4	54.6 ± 16.9	53.7 ± 15.6	54.3 ± 16.7
Missing	13	11	2	0
Sex				
Female	849 (58)	308 (63)	278 (56)	263 (56)
Male	611 (42)	183 (37)	222 (44)	206 (44)
Geographic division				
Mosoriot	482 (33)	158 (32)	205 (41)	119 (25)
Turbo	978 (67)	333 (68)	295 (59)	350 (75)
Enrollment diastolic BP, mm Hg	89.7 ± 12.0	89.0 ± 12.3	90.4 ± 12.1	89.7 ± 11.5
Missing	122	69	49	4
Enrollment systolic BP, mm Hg*	159.4 ± 19.5	158.4 ± 19.6	$\textbf{158.3} \pm \textbf{20.3}$	161.3 ± 18.5
Missing	122	69	49	4
Employment status*				
No job	307 (21)	84 (17)	79 (16)	144 (31)
Farmer	733 (50)	284 (58)	250 (50)	199 (42)
Business person	189 (13)	64 (13)	64 (13)	61 (13)
Public sector employee	54 (4)	13 (3)	25 (5)	16 (3)
Student	4 (0)	1 (0)	2 (0)	1 (0)
Other	151 (10)	34 (7)	72 (14)	45 (10)
Missing	22 (2)	11 (2)	8 (2)	3 (1)
Monthly earnings (Kenyan shillings per month)				
No job	307 (21)	84 (17)	79 (16)	144 (31)
<5,000	720 (49)	264 (54)	259 (52)	197 (42)
≥5,000 and <10,000	198 (14)	55 (11)	77 (15)	66 (14)
≥10,000 and <20,000	79 (5)	28 (6)	26 (5)	25 (5)
≥20,000 and <30,000	36 (2)	7 (1)	16 (3)	13 (3)
≥30,000	28 (2)	10 (2)	12 (2)	6 (1)
Missing	92 (6)	43 (9)	31 (6)	18 (4)
Have National Health Insurance?*				
No	1,217 (83)	427 (87)	417 (83)	373 (80)
Yes	214 (15)	53 (11)	70 (14)	91 (19)
Missing	29 (2)	11 (2)	13 (3)	5 (1)
Physical activity: >150 moderate- equivalent min per week*				
No	411 (28)	123 (25)	136 (27)	152 (32)
Yes	986 (68)	347 (71)	344 (69)	295 (63)
Missing	63 (4)	21 (4)	20 (4)	22 (5)
Current tobacco use*				
No	1,325 (91)	458 (93)	448 (90)	419 (89)
Yes	113 (8)	23 (5)	43 (9)	47 (10)
Missing	22 (2)	10 (2)	9 (2)	3 (1)
Current alcohol use*				
No	1,245 (85)	441 (90)	406 (81)	398 (85)
Yes	193 (13)	39 (8)	86 (17)	68 (14)
Missing	22 (2)	11 (2)	8 (2)	3 (1)

Values are mean \pm SD, n, or n (%). *p < 0.05 for a difference between any 2 study arms. BP = blood pressure; LARK = Optimizing Linkage and Retention to Hypertension Care in Rural Kenya.

We hypothesized that the LARK intervention would affect follow-up SBP by changing linkage to hypertension care. To test that causal hypothesis, we conducted a causal mediation analysis by dividing the total intervention effect into the direct

and indirect (mediated by linkage to care) effects (22), using the mediation package in R software (23).

RESULTS

A total of 1,460 individuals (58% women) were enrolled (491 usual care, 500 paper-based, 469 smartphone) (Central Illustration). Average baseline SBP was 159.4 mm Hg and DBP was 89.7 mm Hg. Full baseline characteristics are shown in Table 1. Notably, 21% of individuals reported no formal employment, and nearly 50% reported monthly earnings <5,000 Kenyan Shillings (approximately U.S. \$50) per month. Although individuals in the smartphone arm were more likely to report no formal employment, the combined percentage of individuals either unemployed or earning <\$50 per month was equivalent across all arms. Only 15% reported having enrolled in the Kenyan governmental national health insurance plan. Additional baseline characteristics are provided in Online Table 1.

Follow-up measures of linkage were available for 1,128 (77%) participants. Our primary linkage outcome was "linkage overall," given the challenges described earlier about relying solely on the AMRS clinical data. Linkage to care was 49% overall (Table 2), with significantly greater linkage in the usual care and smartphone arms (Table 3). Linkage according to the AMRS clinical data was 15%.

Follow-up information for BP was available for 1,106 individuals (76%). Average overall follow-up SBP and DBP were 149.9 and 90.8 mm Hg, respectively. The intraclass correlation coefficient of SBP was estimated to be 0.01 in an unadjusted, complete-case model. The participants in the smartphone arm experienced a slightly greater reduction in SBP than did the usual care group (–13.1 mm Hg vs. –9.7 mm Hg), but this difference was not statistically significant in the fully adjusted model (difference, –2.13 mm Hg; 95% confidence interval: –4.89 to 0.42). BP control (<140/90 mm Hg) was achieved in 26% of participants with follow-up BP data, and there was no statistically significant difference across the study arms.

Mediation analysis revealed that linkage to care contributed to SBP change (Central Illustration, Table 3). For the smartphone versus usual care comparison, the direct effect was estimated at –1.70 mm Hg and the indirect (mediated) effect was –0.43 mm Hg. For the smartphone versus paper-based comparison, the direct and indirect effects were –1.07 mm Hg and –1.00 mm Hg, respectively. Additional outcome measures are provided in Online Table 2.

DISCUSSION

In this cluster randomized trial in western Kenya, CHWs equipped with a tailored behavioral communication strategy and a smartphone-based mHealth tool led to improved linkage to hypertension care but not statistically significant improvement in SBP reduction among hypertensive individuals, compared with usual care. Some of the SBP effect was mediated by linkage to care. Participants in all 3 arms of the trial experienced substantial reductions in SBP. Although not statistically significant, the smartphone-based intervention tended toward modestly greater improvement in SBP reduction. It is quite plausible that, with a larger sample size, a statistically significant improvement would have resulted. Given the substantive absolute declines in SBP observed in our study, substantial cardiovascular and mortality benefit would be expected from a clinical and population perspective (24).

Other studies using CHWs for hypertension and other noncommunicable disease care have demonstrated a positive impact of CHW-based interventions. For instance, trained NPHWs can accurately perform cardiovascular risk screening to identify high-risk patients and counsel them on behavior change (25-27). NPHWs can also screen for oral and cervical cancers (28,29); screen and treat depression (30,31); prescribe and dispense medications for conditions, including epilepsy, diabetes, hypertension, and asthma (32-34); and track and improve patients' adherence to these therapies. In our study, the usual care arm outperformed historical comparisons and our expectations (5). It is quite possible that the context of the trial contributed to better-than-expected performance of the usual care CHWs, thus challenging comparisons between intervention arms and usual care. Although we note that all arms of the trial generated a substantive decline in SBP among participants, the lack of a statistically significant comparison across arms also indicates a need to consider other innovative ways to deliver hypertension care while incorporating CHWs into the management team.

Our smartphone-based intervention did improve linkage to hypertension care compared with both the usual care and paper-based arms, which did contribute to SBP reduction. Other interventions to improve linkage to care include facilitating transportation and reducing transport costs (35), portable care delivered outside the health facility in community and group settings (5), and improved health insurance coverage (36). Future interventions to improve linkage and retention to hypertension

TABLE 2 Summary of Outcome Measures Overall and by Trial Arm							
Outcome Variable	Total (N = 1,460)	Usual Care (n = 491)	Paper-Based (n = 500)	Smartphone (n = 469)			
Link in 1 yr, captured in AMRS							
No	1,048 (72)	312 (64)	385 (77)	351 (75)			
Yes	219 (15)	100 (20)	63 (13)	56 (12)			
Unable to capture in AMRS	193 (13)	79 (16)	52 (10)	62 (13)			
Linkage overall							
No	414 (28)	117 (24)	186 (37)	111 (24)			
Yes	714 (49)	245 (50)	217 (43)	252 (54)			
Unable to ascertain	332 (23)	129 (26)	97 (19)	106 (23)			
Follow-up systolic BP, mm Hg	149.9 ± 21.8	150.0 ± 22.9	150.2 ± 21.6	149.4 ± 20.8			
Missing	354	136	105	113			
Follow-up diastolic BP, mm Hg	90.8 ± 13.5	90.1 ± 13.7	91.0 ± 14.1	91.3 ± 12.7			
Missing	354	136	105	113			
Change in systolic BP, mm Hg	-10.4 ± 23.3	-9.7 ± 25.1	-8.4 ± 24.0	-13.1 ± 20.5			
Missing	451	188	147	116			
Change in diastolic BP, mm Hg	0.7 ± 14.2	0.1 ± 14.7	$\textbf{0.4} \pm \textbf{15.2}$	1.5 ± 12.7			
Missing	451	188	147	116			
Controlled BP at follow-up							
No	817 (56)	256 (52)	289 (58)	272 (58)			
Yes	289 (20)	99 (20)	106 (21)	84 (18)			
Missing	354	136	105	113			
Days between enrollment and follow-up	552.8 ± 181.4	615.6 ± 197.2	580.2 ± 184.9	459.8 ± 111.0			
Missing	354	136	105	113			

Values n (%), mean \pm SD, or n.

 $AMRS = A cademic \ Model \ Providing \ Access \ to \ Healthcare \ Partnership \ Medical \ Records \ System; \ BP = blood \ pressure.$

care should therefore consider a multicomponent approach that incorporates several of these strategies. Indeed, linkage and retention to hypertension care remain substantial problems for hypertension management in many parts of the world (37).

One of the key baseline factors in our study population was the notable poverty and lack of health insurance. More than one-half of our participants were either unemployed or earned less than \$1.50/day. More than 80% had no health insurance. In the face of that economic adversity and lack of financial protection, it is not surprising that our intervention had limited additional impact compared with usual care. Neither the tailored behavioral communication strategy nor the smartphone-based tool intervened directly on the economic reality of our study participants, a reality that has been shown to affect healthseeking behavior and linkage to care (38). In response to this adverse economic context, we subsequently developed other interventions that combine economic and health components (e.g., the BIGPIC [Bridging Income Generation with GrouP Integrated Care] trial; NCT02501746), to intervene on those structural factors more directly (39). The results of the BIGPIC trial will help to illuminate the impact of

TABLE 3 Summary of Effects of Intervention on Linkage to Care, SBP, and BP Control: Mediation Analysis Presented, Including Direct, Indirect, and Total Effect

	Paper-Based vs. Usual Care	Smartphone vs. Usual Care	Smartphone vs. Paper-Based
Linkage to care, OR (95% CI)			
Unadjusted	0.65 (0.44 to 0.94)	1.28 (0.75 to 2.10)	1.99 (1.28 to 3.03)
Fully adjusted	0.63 (0.43 to 0.91)	1.21 (0.70 to 2.01)	1.95 (1.23 to 3.01)
SBP, difference (95% CI)			
Partially adjusted*	-0.49 (-4.06 to 2.81)	-2.08 (-4.84 to 0.53)	-1.59 (-4.67 to 1.70)
Total effect (fully adjusted)†	-0.06 (-3.61 to 3.20)	-2.13 (-4.89 to 0.42)	-2.07 (-5.14 to 1.12)
Direct effect	-0.48 (-3.85 to 2.64)	-1.70 (-4.27 to 0.81)	-1.07 (-4.03 to 1.91)
Indirect (mediated) effect	0.43 (0.05 to 0.89)	-0.43 (-1.11 to 0.16)	-1.00 (-1.71 to -0.39)
BP control, OR (95% CI) (fully adjusted)	0.97 (0.63 to 1.42)	0.95 (0.61 to 1.38)	1.00 (0.69 to 1.40)

^{*}Incorporates multiple imputation and the bootstrap, and partially adjusted for baseline SBP and follow-up time. †Incorporates multiple imputation and the bootstrap and fully adjusted for: baseline SBP, follow-up time, age, sex, enrollment in national health insurance, tobacco and/or alcohol use, employment status, physical activity, awareness of hypertension status, and geographic division.

interventions that tackle the economic reality of individuals residing in low-resource settings worldwide.

The global burden of hypertension and other noncommunicable diseases is substantial and increasing, especially in low- and middle-income countries. Each step in the clinical cascade, including linkage and retention to care, can benefit from improved implementation. The LARK Hypertension Study demonstrates that CHWs have the potential to improve linkage to care, which can contribute to improved BP. Our study adds to the growing literature demonstrating that the infrastructure and strategies that have been established for the control of communicable diseases-including community-based screening, task redistribution within teams, partnerships with local providers, and medical informatics-can serve as a foundation for an integrated delivery system approach to the control of noncommunicable chronic conditions (40). Our results also highlight the need for further innovations to improve hypertension management and control in low-resource settings worldwide (41).

study LIMITATIONS. One significant challenge was the initial reliance on clinical data stored in the AMRS, a strategy that ultimately was deemed to have several shortcomings. Although we rectified the situation and created a fully stand-alone research database that assessed self-reported linkage, there remain limitations to self-reported data, as is well known. Second, there were missing data, both at baseline and at follow-up, which affected our analytic approach and influenced the imputation methods used. Third, there were some significant baseline differences across trial arms, likely the result of the cluster randomized nature of the trial, which necessitated an analytic approach that accounted for those

baseline differences. Fourth, there was differential time to follow-up across the arms that required analytic rectification. Fifth, because of the same limitations we have described for the linkage determination by AMRS, we unfortunately do not have access to medication prescribing data for the participants derived from the clinical records. Although we do have data on self-reported medication use, we are not confident in the reliability of those self-reported data and therefore did not include medication prescription information in this report. Finally, the individuals who participated in the community-based BP screening activities may not be fully representative of the general population.

CONCLUSIONS

A strategy combining tailored behavioral communication and mHealth for CHWs led to improved linkage to care, with modest, but not statistically significant, improvement in SBP reduction among individuals with elevated BP in western Kenya. Further innovations to improve engagement in the hypertension care cascade and hypertension control are needed.

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BP = blood pressure; CI = confidence interval; DBP = diastolic blood pressure; OR = odds ratio; SBP = systolic blood pressure.

PERSPECTIVES

COMPETENCY IN SYSTEMS-BASED PRACTICE:

CHWs in rural Africa who are equipped with behavioral and communication strategies can improve linkage to hypertension care.

TRANSLATIONAL OUTLOOK: More implementation research is needed to develop strategies that translate linkage to hypertension care into better long-term clinical outcomes.

REFERENCES

- 1. Lewington S, Clarke R, Qizilbash N, Peto R, Collins R. Age-specific relevance of usual blood pressure to vascular mortality: a meta-analysis of individual data for one million adults in 61 prospective studies. Lancet 2002; 360:1903-13.
- **2.** Stanaway JD, Afshin A, Gakidou E, et al. Global, regional, and national comparative risk assessment of 84 behavioural, environmental and occupational, and metabolic risks or clusters of risks for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study 2017. Lancet 2018;392: 1933-94
- **3.** Chow CK, Teo KK, Rangarajan S, et al. Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries global prevalence and control of hypertension global prevalence and control of hypertension. JAMA 2013;310:959–68.
- 4. Khatib R, Schwalm J-D, Yusuf S, et al. Patient and healthcare provider barriers to hypertension awareness, treatment and follow up: a systematic review and meta-analysis of qualitative and quantitative studies. PLoS One 2014;9: e84238.
- **5.** Pastakia S, Manyara S, Vedanthan R, et al. Impact of Bridging Income Generation with Group Integrated Care (BIGPIC) on hypertension and diabetes in rural Western Kenya. J Gen Intern Med 2017;32:540–8.
- **6.** Moodley J. Maternal deaths associated with hypertension in South Africa: lessons to learn from the Saving Mothers report, 2005-2007. Cardiovasc J Afr 2011;22:31-5.
- **7.** Ogedegbe G, Plange-Rhule J, Gyamfi J, et al. Health insurance coverage with or without a nurse-led task shifting strategy for hypertension control: a pragmatic cluster randomized trial in Ghana. PLoS Med 2018;15:e1002561.
- **8.** Joshi R, Alim M, Kengne AP, et al. task shifting for non-communicable disease management in low and middle income countries a systematic review. PLoS One 2014;9:e103754.
- **9.** Prasad B, Muraleedharan V. Community Health Workers: A Review of Concepts, Practice and Policy Concerns. HRH Global Resource Center. 2007. Available at: https://www.hrhresourcecenter.org/

- hosted_docs/CHW_Prasad_Muraleedharan.pdf. Accessed August 13, 2019.
- **10.** He J, Irazola V, Mills KT, et al. Effect of a community health worker-led multicomponent intervention on blood pressure control in low-income patients in Argentina: a randomized clinical trial. JAMA 2017;318:1016–25.
- **11.** Vedanthan R, Kamano JH, Naanyu V, et al. Optimizing linkage and retention to hypertension care in rural Kenya (LARK hypertension study): study protocol for a randomized controlled trial. Trials 2014;15:143.
- **12.** Einterz RM, Kimaiyo S, Mengech HN, et al. Responding to the HIV pandemic: the power of an academic medical partnership. Acad Med 2007;82: 812–8.
- **13.** Bloomfield GS, Kimaiyo S, Carter EJ, et al. Chronic noncommunicable cardiovascular and pulmonary disease in sub-Saharan Africa: an academic model for countering the epidemic. Am Heart J 2011:161:842-7.
- **14.** Naanyu V, Vedanthan R, Kamano JH, et al. Barriers influencing linkage to hypertension care in Kenya: qualitative analysis from the LARK hypertension study. J Gen Intern Med 2016;31:304-14.
- **15.** World Health Organization. WHO STEPS Surveillance Manual: The WHO STEPwise Approach to Chronic Disease Risk Factor Surveillance. Geneva, Switzerland: World Health Organization, 2005.
- **16.** Riddell MA, Edwards N, Thompson SR, et al. Developing consensus measures for global programs: lessons from the Global Alliance for Chronic Diseases Hypertension research program. Global Health 2017;13:17.
- **17.** Whitworth JA. 2003 World Health Organization (WHO)/International Society of Hypertension (ISH) statement on management of hypertension. J Hypertens 2003;21:1983–92.
- **18.** Chobanian AV, Bakris GL, Black HR, et al. The seventh report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure: the JNC 7 report. JAMA 2003;289:2560–72.
- **19.** Clinical Management and Referral Guidelines. Vol III. Nairobi, Kenya: Ministry of Medical Services and Ministry of Public Health and Sanitation, 2010.

- **20.** Schomaker M, Heumann C. Bootstrap inference when using multiple imputation. Stat Med 2018:37:2252-66.
- 21. Multivariate Imputation by Chained Equations.

 Available at: https://cran.r-project.org/web/
 packages/mice/index.html. Accessed July 12,
 2019
- **22.** Imai K, Keele L, Yamamoto T. Identification, Inference and Sensitivity Analysis for Causal Mediation Effects. Stat Sci 2010;25:51–71.
- **23.** Tingley D, Yamamoto T, Hirose K, Keele L, Imai K. mediation: R Package for Causal Mediation Analysis. J Stat Software 2014;59:1–38.
- **24.** Ettehad D, Emdin CA, Kiran A, et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. Lancet 2016;387:957-67.
- **25.** Abegunde DO, Shengelia B, Luyten A, et al. Can non-physician health-care workers assess and manage cardiovascular risk in primary care? Bull World Health Organ 2007;85:432-40.
- **26.** Gaziano TA, Abrahams-Gessel S, Denman CA, et al. An assessment of community health workers' ability to screen for cardiovascular disease risk with a simple, non-invasive risk assessment instrument in Bangladesh, Guatemala, Mexico, and South Africa: an observational study. Lancet Glob Health 2015;3:e556-63
- **27.** Khan M, Lamelas P, Musa H, et al. Development, testing, and implementation of a training curriculum for nonphysician health workers to reduce cardiovascular disease. Glob Heart 2018;13: 93–100.e1.
- **28.** Gajalakshmi CK, Krishnamurthi S, Ananth R, Shanta V. Cervical cancer screening in Tamilnadu, India: a feasibility study of training the village health nurse. Cancer Causes Control 1996;7: 520–4.
- **29.** Warnakulasuriya K, Ekanayake A, Sivayoham S, et al. Utilization of primary health care workers for early detection of oral cancer and precancer cases in Sri Lanka. Bull World Health Organ 1984;62: 243–50.
- **30.** Patel V, Weiss HA, Chowdhary N, et al. Lay health worker led intervention for depressive and anxiety disorders in India: impact on clinical and disability outcomes over 12 months. Br J Psychiatry 2011;199:459-66.

■, 2019: ■ - ■

- **31.** Weobong B, Weiss HA, McDaid D, et al. Sustained effectiveness and cost-effectiveness of the Healthy Activity Programme, a brief psychological treatment for depression delivered by lay counsellors in primary care: 12-month follow-up of a randomised controlled trial. PLoS Med 2017;14: e1002385
- **32.** Kengne AP, Fezeu L, Awah PK, Sobngwi E, Mbanya JC. Task shifting in the management of epilepsy in resource-poor settings. Epilepsia 2010; 51:931–2.
- **33.** Kengne AP, Sobngwi E, Fezeu LL, et al. Nurseled care for asthma at primary level in rural sub-Saharan Africa: the experience of Bafut in Cameroon. J Asthma 2008;45:437-43.
- **34.** Labhardt ND, Balo JR, Ndam M, Grimm JJ, Manga E. Task shifting to non-physician clinicians for integrated management of hypertension and diabetes in rural Cameroon: a programme assessment at two years. BMC Health Serv Res 2010;10:339.
- **35.** Kotwani P, Balzer L, Kwarisiima D, et al. Evaluating linkage to care for hypertension after

community-based screening in rural Uganda. Trop Med Int Health 2014;19:459-68.

- **36.** Fang J, Zhao G, Wang G, Ayala C, Loustalot F. Insurance status among adults with hypertension-the impact of underinsurance. J Am Heart Assoc 2016;5:e004313.
- **37.** Geldsetzer P, Manne-Goehler J, Marcus M-E, et al. The state of hypertension care in 44 low-income and middle-income countries: a cross-sectional study of nationally representative individual-level data from 1·1 million adults. Lancet 2019 Jul 18 [E-pub ahead of print].
- **38.** Musinguzi G, Anthierens S, Nuwaha F, Van Geertruyden JP, Wanyenze RK, Bastiaens H. Factors influencing compliance and health seeking behaviour for hypertension in Mukono and Buikwe in Uganda: a qualitative study. Int J Hypertens 2018;2018:8307591.
- **39.** Vedanthan R, Kamano JH, Lee H, et al. Bridging Income Generation With Group Integrated Care for cardiovascular risk reduction:

rationale and design of the BIGPIC study. Am Heart J 2017;188:175-85.

- **40.** Rabkin M, El-Sadr WM. Why reinvent the wheel? Leveraging the lessons of HIV scale-up to confront non-communicable diseases. Glob Public Health 2011;6:247-56.
- **41.** Vedanthan R, Bernabe-Ortiz A, Herasme OI, et al. Innovative approaches to hypertension control in low- and middle-income countries. Cardiol Clin 2017;35:99-115.

KEY WORDS community health workers, hypertension, Kenya, linkage to care, smartphone technology, tailored behavioral communication

APPENDIX For supplemental figures, tables, and a video, please see the online version of this paper.