BMJ Open

Results from an innovative model of hypertension care: The ComHIP Cohort study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026799
Article Type:	Research
Date Submitted by the Author:	02-Oct-2018
Complete List of Authors:	Adler, Alma; London School of Hygiene & Tropical Medicine, Department of Non-communicable Disease Epidemiology; Harvard Medical School Laar, Amos; School of Public Health, University of Ghana, Department of Population, Family & Reproductive Health Prieto-Merino, David; London School of Hygiene and Tropical Medicine, Department of Non-communicable Disease Epidemiology Der, Reina; Family Health International Mangortey, Debbie ; Family Health International Dirks, Rebecca; Family Health International Lamptey, Peter; London School of Hygiene & Tropical Medicine, Department of Non-communicable Disease Epidemiology Perel, Pablo; London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology
Keywords:	Hypertension < CARDIOLOGY, cohort, EPIDEMIOLOGY

Results from an innovative model of hypertension care: The ComHIP Cohort study

Alma J Adler[12*], Amos K Laar[3*], David Prieto-Merino[1], Reina M. M. Der[4], Debbie Mangortey[4], Rebecca Dirks[5], Peter Lamptey[1], Pablo Perel[1]

***Co-first authors**

Correspondence:
Dr. Alma J Adler
alma.adler@lshtm.ac.uk

[1]Department of Non-communicable Disease Epidemiology. London School of Hygiene & Tropical Medicine. Keppel St, London. WC1E 7HT

[2]Department of Global Health and Social Medicine, Harvard Medical School. Boston, MA, United States

[3]Department of Population, Family, & Reproductive Health, School of Public Health, University of Ghana, LG 13, Legon, Accra, Ghana.

[4]Family Health International 360, Accra, Ghana

[5]Family Health International 360, Washington DC, United States.

Alma J Adler alma.adler@lshtm.ac.uk
Amos K Laar alaar@ug.edu.gh
David Prieto -Merino david.prieto@lshtm.ac.uk
Reina M. M. Der RDer@fhi360.org
Debbie Mangortey DMangortey@fhi360.org
Rebecca Dirks rdirks@fhi360.org
Peter Lamptey plamptey@fhi360.org
Pablo Perel pablo.perel@lshtm.ac.uk

Word count: 4435

Abstract:

Objectives: to present an evaluation of the Community-Based Hypertension Improvement Project (ComHIP).

Setting: Lower Manya Krobo, Eastern Region, Ghana.

Participants: All adult hypertensive community members, except pregnant women, were eligible for inclusion in the study. We enrolled 1339 participants, 69% of which were female. 552 had a six-month visit, and 338 had a 12-month visit.

Interventions: Community based CVD nurses were trained by Family Health International (FHI360). CVD nurses confirmed diagnoses of known hypertensives and newly screened individuals. Participants were treated according to clinical guidelines established through the project's Technical Steering Committee.

Primary outcome: Hypertension control defined as blood pressure under 140/90 mm Hg. Secondary outcomes: Changes in blood pressure and knowledge of risk factors for hypertension.

Results: After one year of intervention 72% (95% CI 67%, 77%) of participants had their hypertension under control. Systolic BP was reduced by -12.2 mmHg (95%CI 14.4, -10.1) and diastolic BP by -7.5 mmHg (95%CI 9.9, 6.1). Factors associated with remaining in the programme for 12-months included education, older age, hypertension under control at enrollment, and enrollment date. The majority of patients who remained in the programme were on treatment, with two-thirds taking at least two medications

Conclusions: Patients retained in ComHIP had increased BP control. However, high loss to follow-up limits potential public health impact of these types of programmes. To minimize impact of externalities, programmes should include standard procedures and back-up systems to maximize the possibility that patients stay in the programme.

Keywords:

Hypertension, Ghana, Community based cohort study.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ComHIP is a large cohort study testing a community based model of hypertension care
- Trained community based cardiovascular nurses conducted screening, diagnosis and management of hypertension patients
- Patients were sent three types of SMS, daily reminders to take their medications, appointment reminders, and weekly health education messages
- Blood pressure was checked with a minimum of three serial readings at regular intervals, but at a minimum of 6-monthly intervals
- The study showed important reductions in blood pressure that require further replication

INTRODUCTION:

Globally, raised systolic blood pressure (SBP) is one of the greatest risk factors for disability (GBD, 2017). Hypertension is generally considered to be the level of raised blood pressure (BP) where medications show a reduction in clinical events in randomized trials. This is generally accepted as ≥140 SBP mmHg or ≥90 diastolic mmHg (DBP)[1].

Evidence shows that lowering hypertensive individual's blood pressure with accessible drugs reduces the risk of further cardiovascular events; with a reduction in stroke by an estimated 35–40% and a myocardial infarction and heart failure reduced by 20–25% reduction [2-4]. Whilst average age-standardised BP is decreasing in most high-income countries, it is increasing in most low and middle income countries (LMICs) [5] with 32% to 50% of adults estimated to be hypertensive in sub-Saharan Africa [6].

The Prospective Urban Rural Epidemiology (PURE) study showed that despite high levels of hypertension worldwide, only 34% of Africans are aware of their hypertension status, only 31.3% receive any treatment and only 6.5% have their blood pressure under control .[7] Our recent study of hypertension prevalence in the Lower Manya Krobo, Ghana, showed that only 2.1% of hypertensives had their blood pressure under control [8].

Because of the great burden of hypertension in Sub-Saharan Africa and the poor rate of hypertension control, innovative methods for hypertension management are needed. Launched in 2015, the Community-Based Hypertension Improvement Project (ComHIP) introduced an innovative model for hypertension control at the community level. ComHIP is a public-private partnership between the Ghana Health Service, FHI 360 and the Novartis Foundation.

The aim of ComHIP is to improve hypertension management and control in the Lower Manya Krobo district in the Eastern Region of Ghana. The programme includes six components (Supplementary Figure 1), aimed at increasing access to hypertension services at the community level. Screening in the community is provided by Cardiovascular Disease (CVD) nurses and Community Health Officers (CHOs), as well as through local private sector drug shops called licensed chemical sellers (LCS). Ongoing hypertension management is provided by CVD nurses or, for those with co-morbidities or severe conditions, at district hospitals. Patients are encouraged to routinely monitor their blood pressure by having their BP measured at a LCS. The various service providers are linked through a cloud-based system which revolve around bringing hypertension care into the community. Physicians, Community based CVD nurses, CHOs, and LCS staff were trained by FHI 360 to provide specific services. For instance, CVD nurses conduct hypertension screening, and confirmation of hypertension diagnosis, staging of degree of hypertension, assessment of other CVD risk factors, counselling, monitoring and follow up and trained LCS conduct community BP screening and awareness raising. Further information is found in the supplementary material.

CommCare is a vital component of ComHIP. It serves as a case management system, referral tool, and job aid for providers. The CommCare database is linked with a SMS platform to automatically send daily adherence reminders, weekly healthy living tips, and consultation and prescription refill reminders to enrolled patients. These messages are sent via text or voice SMS with four language choices. The programme is described in more detail elsewhere [8]. Briefly, through CommCare patients diagnosed with severe hypertension or co-existing conditions are automatically referred to a physician. All patients enrolled in ComHIP receive SMS daily for medication reminders, weekly for health education, and upon need for appointment and screening reminders. CommCare also provides a cloud based health records system that links patients' records with the SMS system. Due to operational problems, there was a break in service in CommCare that began on 12 May 2016 for a period of at least three months.

The ComHIP Programme is being independently evaluated by the University of Ghana School of Public Health and the London School of Hygiene & Tropical Medicine with a mixed method approach through a series of quantitative and qualitative studies. These studies include repeat cross-sectional surveys within the intervention and comparison districts to track overall awareness and prevalence of hypertension; a cohort of hypertensive persons included in ComHIP to assess hypertension control; a cost-effectiveness evaluation; a study to assess the level of patient-centeredness within the programme; and a qualitative assessment of ComHIP stakeholders. In this paper we report the results of the cohort study.

Objectives

The objective of this study was to evaluate the effectiveness of ComHIP for controlling hypertension in hypertensive patients enrolled into the ComHIP programme.

METHODS:

Study design

The study was a prospective cohort study which included all patients recruited into the ComHIP Programme.

Setting

The study was conducted in Lower Manya Krobo, a municipality in the Eastern region of Ghana. This is a peri-urban setting approximately two hours from the national capital, Accra with a population of approximately 89,246, of whom 84% live in urban areas .[9] Recruitment began October 2015 and ended in December 2016.

Participants

Patients were enrolled into the programme if 1) they were known hypertensives or 2) had an elevated blood pressure reading at any ComHIP screening. Any individual living in Lower Manya Krobo 18 years or older was eligible, except pregnant women. Community members were screened by CHOs, LCS, or CVD nurses, using Omron M6 BP monitors. The average of three serial readings was used to confirm hypertension diagnosis. Patients who were at risk of hypertension (SBP ≥120, but <140) were given health education. All patients with SBP≥140 or DBP ≥90 were referred to a CVD nurse for diagnosis. Patients with SBP ≥180 or DBP ≥110 were enrolled and referred to the physician for urgent care. Patients that were considered to have severe hypertension, (SBP ≥180 or DBP ≥110 or SBP between 160 – 179 or DBP 100 – 109 with one or more risk factors, or any evidence of organ damage) were referred for management by a physician at one of the district hospitals, all other patients were managed by CVD nurses.

Hypertensive individuals were enrolled and followed for at least one year. All patient interactions (with LCS, CHOs, CVD nurses, community and hospital pharmacist and doctors) were recorded and uploaded through the CommCare platform. Patients were requested to present for appointments at the following intervals; monthly BP monitoring appointments, monthly, bi-monthly or quarterly review visits (depending on risk factors and personal factors); and six-monthly follow up assessments. Participants were recruited from October 2015 until December 2016, and followed

through December 2017. Guidelines for patient visits can be found in the supplementary materials (Supplementary Table 1 and Supplementary Figure 2).

All enrolled participants were treated based on clinical guidelines established through the project's Technical Steering Committee, which included senior members of the GHS. The treatment goal was to improve blood pressure of all patients to below 140/90mmHg. Participants were initiated onto drug therapy and supplemented with non-drug therapy (lifestyle modification including low salt diets, increased fruit and vegetable diet, reduction in alcohol consumption, smoking cessation and regular aerobic exercise) irrespective of their risk level. The decision to initiate a monotherapy or multiple drug therapy depended largely on the level at which the participants BP was above goal and the overall risk level of patients. Recommended drugs and dosages are found in supplementary Table 2. Patient's response to antihypertensive were reviewed every three months and modified based on recommended guidelines if required.

Variables

Main outcomes:

The main outcomes of interest were hypertension control (<140/90), and changes in systolic and diastolic blood pressure. Because of the low follow up rate, we also used appointment at six months, and appointment at 12 months as outcomes of interest.

Other variables:

Other variables included demographic factors including age, gender and marital status; risk factors such as body -mass index (BMI), awareness of hypertension, having hypertension under control prior to enrolment, and having previous diagnoses of other heart diseases, and socioeconomic factors. A full list of variables is found in Table 1.

Data collection

Data were collected on blood pressure using standardised protocols. At six and 12 months forms were administered by health care providers to collect information on patient knowledge of risk factors for hypertension and health behaviours.

All data were collected and downloaded from the CommCare platform. Initially data was intended to be analysed from the patient knowledge/behaviour forms used at six-month and 12-month follow up appointments. Due to poor levels of follow up, any appointment between five and seven months after enrolment was used for the six-month appointment analysis, and any appointment between 11 and 13 months after enrolment was used for the 12-month appointment analysis.

Sample size

This cohort study included all the patients recruited in the ComHIP programme and a specific sample size was not calculated. However, in the protocol we assumed that the total district population is about 90,000; about 30,000, of whom are adults, and about 36% [12000] are estimated to be hypertensive. Assuming that about 10% of the adults with hypertension in the district will be included in the ComHIP Programme we would have a cohort of 1,200 hypertensive patients.

We estimated that a cohort study of 1200 hypertensive patients would provide a power greater than 90% (with an alpha error of 0.05) to detect a two-fold increase of control of hypertension (from 4% to 8%).

Patient and Public Involvement

Community members, including community leaders, were first involved through a stakeholder workshop. In this workshop, community members shared their thoughts, knowledge, and concerns about health in general, NCD-related conditions, and access to healthcare. Furthermore, community members were made aware of the hypertension project planned to be initiated in their community. This information was considered in finalizing the design of the service delivery model and the development of prevention, education, and behaviour change messages.

Patients were recruited into the project through free screening offered at 1) local drug shops, names Licensed Chemical Sellers; 2) Community Health Planning Service (CHPS) sites; or 3) Community pharmacies. There were community screening activities and radio programs through which community members were educated on the project and hypertension in general. In addition, ComHIP staff conducted annual stakeholder meetings to provide updates to community members on the project progress.

Statistical methods

We recoded exposures to reduce the number of levels and of missing values: For all the previous diagnosis / awareness: We have coded "missing" or "not known" or "no answer" as 0, so that value 1 always means "Patient knows of a previous diagnosis" while value 0 means anything else (patient does not know or answer is missing). Because there were few previous diagnoses of each specific event (MI, stroke, diabetes…) we created a variable with value 1 if any diagnosis was present and 0 if none was present.

For education, we assumed that those that did not know (48) or did not respond (26) did not have previous formal education (the largest group). We then grouped education in 4 levels: 1) no formal education, 2) primary (completed or not) 3) secondary (completed or not) and 4) higher (university)

For marital status, we made 4 categories: 1) Never married 2) married or cohabiting 3) separated or divorced 4) widowed.

We described the distribution of each variable at baseline, six-months and 12-months follow up, although comparisons cannot be done directly due to the large number of individuals that did not have follow up. To study what variables might affect the patient staying for 12-months in the programme we ran a logistics regression for the binary outcome variable: "patient had 12-month visit (Y/N)".To consider the loss to follow up (patterns of visits), we separated the individuals into four different groups: (A) those individuals that did not come to any follow up visit, (B) those that came only to the 6-month visit, (C) those that came only to the 12-month visit, and (D) those that came to both follow up visits.

We described the absolute values of blood pressure (SBP and DBP), the proportion of patients with blood pressure under control and the distribution of hypertension stages for each of these groups in each of the visits. We estimated the average changes of blood pressure for each group at each follow up visit and we compared the changes between groups with Student's t-tests. We compared the mean of SBP and DBP between the groups with ANOVA models. To compare the proportion of

patients with HT control or the distribution of hypertension stages between groups we used chi-square tests. To test the changes of variables within groups we used paired t-tests for continuous variables and marginal homogeneity tests for categorical variables.

Ethical Approval

Ethical approval was granted by the Institutional Review Boards (IRBs) of LSHTM (LSHTM Ethics Ref: 10,152), the Ghana Health Service (ID NO. GHS-ERC 04/01/15), and the University of Ghana at Noguchi Memorial Institute for Medical Research (Ethics clearance # IRB00001276). Written informed consent was obtained from all participants.

RESULTS:

Participants:

A total of 18,339 individuals 18 years and over were screened , 4118 referred to CVD nurses to confirm diagnosis, and of those 1339 were enrolled (76 (5.7%) low risk Grade 1 BP which is SBP 140 – 159 or DBP 90 – 99 without any target organ damages (TODs), co-morbidities or ≥ 2 risk factors), 559 (41.7%) (Moderate risk (SBP 160-179 or DBP 100 – 109 without any TODs, co-morbidities or ≥ 2 risk factors or Grade 1 BP with TODs, co-morbidities or ≥ 2 risk factors), and 704 (52.6%) High risk (Grade 3 which is SBP ≥ 180 or DBP ≥ 101 without any TODs, co-morbidities or ≥ 2 risk factors or Grade 2 BP with TODs, co-morbidities or ≥ 2 risk factors).

General characteristics of the cohort

The average age of the cohort was 58 years. Everyone was enrolled into the cohort by CVD nurses. Of the 1,339 people enrolled in the cohort, 24% were referred to ComHIP by LCS, 45% were referred by CHO, 23% were referred by CVD nurses, 3% were through physicians, and 5% were referred through other channels. 69% of the cohort was female, 31% male. Other characteristics of people enrolled in the cohort are found in Table 1.

Table 1. Characteristics of participants in the study at baseline.

Characteristic	% all	% 6 months	%12 months
Number	1339	552	338
Referred by			
LCS	23.9	23.4	24.3
CHO	45.0	40.8	38.5
CVD Nurse	23.3	25.4	26.9
Other	7.8	10.5	10.4
Sex			
Male	30.8	32.3	30.7
Female	69.2	67.8	69.3
Age class			
30-44	17.9	14.7	13.6
45-54	23.5	21.7	24.3
55-64	27.3	31.9	32.0

65+	31.4	31.7	30.2
hypertension stage			
Normal	26.4	38.6	41.7
Stage I	39	39.9	39.4
Stage II	19.6	14.5	13.0
Stage III	14.9	7.1	5.9
Mean BP			
DBP	90.8	87.6	86.9
SBP	149.0	143.3	141.2
Education			
No formal education	31.5	27.2	27.5
Less than Primary	15.4	16.1	17.8
Completed Primary	26.3	27.0	27.8
Completed secondary	16.1	18.5	14.8
Completed university	1.1	4.7	5.9
Completed other tertiary	4	1.5	2.4
Other or no response	5.6	5.1	3.9
Ethnicity			
Akan	4.2	28.6	21.4
Dangme	69.5	42.2	26
Ewe	22	39.3	22.4
Other or don't know	4.3		
Religion			
Christian	96	97.6	97.9
Muslim	3.2	1.5	1.2
Traditional	0.5	0.4	0.3
None	0.3	0.5	0.6
Marital status			
Never married	5.7	5.1	3.6
Married/Cohabiting	54.4	54.7	57.7
Separated/Divorced	5.5	14.1	15.4
Widowed	26.1	25.9	23.1
no response	0.2	0.2	0.3
Household income			
Less than 728 GHC	18.7	17.0	17.2
728-1020 GHC	17.4	20.8	19.8
1021-1098	6.4	5.3	6.5
1099-1263	5.0	4.9	4.7
More than 1263 GHC	12.3	11.1	11.8
Don't know/no response	40.2	40.9	39.9
Aware of hypertension status			
Never had BP measured	18.7	17.6	16.3
Was not aware	12.9	11.4	10.7
Aware	68.5	70.8	73.1
Taking treatment			
Never diagnosed	31.5	29.2	26.9

No treatment	18	15.0	16.0
Treatment	50.3	55.6	56.8
Don't know	0.2	0.2	0.3
BMI			
Underweight	5.4	4.9	5.0
Normal	43.7	44.8	43.2
Overweight	29.2	30.1	32.5
Obese	21.7	20.3	19.2

*All hypertensive patients enrolled in cohort

**Hypertensive patients with six-month appointment/follow up

**Hypertensive patients with a twelve-month appointment/follow up

Other risk factors:

5.4% of the sample was underweight, 43.7% was normal, 29.2% was overweight and 21.7% was obese. The mean BMI at enrolment in the cohort was 26.1 (95% CI 25.82, 26.4).

We did not analyse smoking, cholesterol or diabetes as only 1% of the sample were smokers, 3.5% reported having had a previous cholesterol test, and only 28% had a previous diabetes test.

Blood Pressure at enrolment

The average SBP was 147.2 (SD 22.1) mmHg, and average DBP was 89.9 (SD 13.3) mmHg. At enrolment 917 (68.5%) had a previous diagnosis of hypertension, of which 654 (71.3%) were already taking some anti-hypertensives, and 297 (32.4%) had their blood pressure under control.

Blood pressure management

Of the 1339 enrolled in the study, 712 (53.2%) did not come for a follow up (group A), 289 (21.6%) had only a six-month visit (group B), 75 (5.6%) had only the 12-month visit (group C) and 263 (19.6%) had both visits (group D). In total only 552 (41%) had a six month follow up appointment, and only 338 (25%) had a 12 month follow up appointment.

Loss to follow up and Characteristics of those who stayed in the study

Patients with their hypertension already under control were more likely to present for care. The variable that showed the greatest association with likelihood of having a six or twelve-month appointment was enrolment month. Participants who enrolled earlier were much more likely to stay in the programme than those who enrolled later (Table 1)

Multivariate analysis suggested that recruitment before 12 May 2016 (one year before the break in service), age, education and hypertension under control in the first visit showed significant associations with having a twelve-month appointment. Recruitment after 12 May 2016 reduced the

chances of coming to further visits, the older the patient and the higher the education level, the higher the chances that the patient would come to the follow up visits. Patients with controlled HT at enrolment were nearly twice as likely to come to follow up visits. None of the other variables showed significant associations (Table 2).

Table 2) multivariate analysis of baseline characteristics associated with staying in the programme 12 months

	OR	95% CI	P value
Enrolled year prior to break	0.46	(0.35, 0.60)	**0.00**
Sex	0.88	(0.63, 1.24)	0.48
Age (one year increments)	1.01	(1.00, 1.02)	**0.03**
BMI	1.00	(0.97, 1.02)	0.90
Edu. reference category: no formal education			
Primary education	1.41	(1.03, 1.93)	**0.03**
Secondary Education	1.13	(0.73, 1.73)	0.59
Higher education	2.42	(1.33, 4.43)	**0.004**
Reference cat: Never married			
Married/cohabitating	1.77	(0.90, 3.48)	0.10
Separated/Divorced	1.86	(0.90, 3.87)	0.10
Widowed	1.27	(0.61, 2.64)	0.52
Household size	1.01	(0.95, 1.07)	0.69
Hypertension control	1.93	(1.47, 2.54)	**<0.001**
Awareness of hypertension	1.00	(1.00, 1.00)	0.97
Hypertension treatment	1.00	(0.99, 1.00)	0.33
Any other previous diagnosis	0.86	(0.69, 1.07)	0.18
Confidence in management of hypertension	1.00	(1.00, 1.01)	0.63

Changes in Blood Pressure

Because 12 month follow up was below 30%, we did not look at overall changes in blood pressure, but we did look at overall changes in blood pressure in those that remained in the study at six and twelve months.

On average, patients who enrolled and presented for a follow-up appointment at around six months, there was a 10.3 mmHg reduction in SBP (95% CI -12.0,-8.6) and a 6.3mmHg reduction in DBP (95% CI -7.2, -5.2) (Table 3). This was greater for all those who had a follow up appointment at one year, when there was a 12.2 mmHg reduction (95% CI -14.4, -10.1) in SBP and a 7.5 mmHg (95% CI 9.9, 6.1) reduction in DBP after one year in the programme (Table 3).

Table-3) Changes in BP means and hypertension control by patterns of visits.

Groups	N	Vis.	SBP		DBP		HT Control
			Mean (SE)	Mean dif. (95%CI)	Mean (SE)	Mean dif. (95%CI)	% (95% CI)
All patients	1339	E	147.2 (0.60)		89.9 (0.36)		31% [29% , 34%]
	552	6m	132.9 (0.80)	-10.3 [-12.0 , -8.6]	81.3 (0.47)	-6.3 [-7.3 , -5.2]	69% [65% , 73%]
	338	12m	128.9 (1.05)	-12.2 [-14.4 , -10.1]	79.4 (0.61)	-7.5 [-8.9 , -6.1]	72% [67%, 77%]
(A) No visits	712	E	150.4 (0.85)		91.7 (0.49)		25% [21% , 28%]
(B) Only 6m	289	E	146.4 (1.28)		89.0 (0.77)		34% [29% , 40%]
		6m	135.7 (1.15)	-10.1 [-13.2 , -8.1]	82.7 (0.68)	-6.3 [-7.8 , -4.8]	61% [55% , 67%]*
(C) Only 12m	75	E	145.9 (2.62)		90.2 (1.63)		36% [25% , 48%]
		12m	132.5 (2.56)	-13.5 [-18.5 , -8.6]	81.0 (1.38)	-9.2 [-12.4 , -6.0]	71% [59% , 81%]*
(D) 6 & 12m	263	E	139.8 (1.18)		86.1 (0.80)		43% [37% , 50%]
		6m	129.8 (1.08)	-10.0 [-12.2 , -7.7]	79.8 (0.63)	-6.3 [-7.8 , -4.8]	77% [72% , 82%]*
		12m	127.9 (1.13)	-11.9 [-14.3 , -9.5]	79.0 (0.67)	-7.1 [-8.6 , -5.5]	72% [66% , 78%]*

* The comparison of these intervals with enrolment visit of the same group produce all p-values <0.0001

E= enrolment

There was also a significant reduction in hypertension stage, with a lower percentage of hypertensive individuals having stage III hypertension over time (Table 4).

Table 4) Distribution of Hypertension Stage in each group in each visit.

The P-values are extracted from: (1) Chi-square tests to compare that row with group A of no follow-up. (2) from marginal homogeneity tests comparing the distribution of the same group in enrolment visit.

Groups by patterns of visits	N	Visit	No HT	Mild	Moderate	Severe	P-value
All patients	1,339	1m	31.0%	39.0%	18.4%	11.6%	
	552	6m	68.7%	19.7%	9.4%	2.2%	< 0.001 (2)
	338	12m	71.9%	19.5%	6.5%	2.1%	< 0.001 (2)
(A) No follow-up	712	1m	24.6%	38.7%	21.5%	15.2%	
(B) Only 6m visit	289	1m	34.3%	39.4%	17.0%	9.3%	0.002 (1)
	289	6m	60.9%	24.2%	12.1%	2.8%	<0.001 (2)
(C) Only 12m visit	75	1m	36.0%	36.0%	17.3%	10.7%	0.167 (1)
	75	12m	70.7%	14.7%	10.7%	4.0%	< 0.001 (2)
(D) 6 & 12m visit	263	1m	43.4%	40.3%	11.8%	4.5%	<0.001 (1)

	263	6m	77.2%	14.8%	6.5%	2.2%	< 0.001 (2)
	263	12m	72.3%	20.9%	5.3%	1.5%	< 0.001 (2)

Awareness

Overall awareness of hypertension status in the overall cohort was 68.5% at enrolment. Individuals who stayed in the programme longer, were more likely to be aware of their hypertension status. 70.8% of individuals who stayed in the programme for six months were aware of their hypertension status, and 73.1% of those who stayed in the programme for 12 months were aware of their hypertension status (Table 1).

Treatment

Treatment increased between enrolment and six and twelve-month appointments. Although only 44.2% of patients were receiving any medication at enrolment, the majority were being treated at six months (90.4%) and at 12 months (92.2%). At enrolment, the majority of patients who were on treatment were taking a calcium channel blocker (CCB) (36% of all patients), but at six months the majority were on diuretics (75.9%) followed by a CCB (69.5%). The same pattern was found at 12 months with 79.8% taking diuretics, and 71.5% taking a CCB (Table 5)

In patients who had a six-month appointment, 24.1% were taking only one medication, 32% were taking two medications, and over 30% were taking more than two medications. In patients who had a 12-month appointment, 23 % were taking one medication, 32.6% were taking two medications, and over 32% were taking more than two medications.

Table 5) treatment pattern in the cohort at enrolment, six months and 12 months with p-values for differences.

Treat	Enrolment	6 month	P change	12 months	P change
Diuretic	21.66%	75.89%	0.00000	79.83%	<0.00001
Calcium CB	36.07%	69.46%	0.00000	71.47%	<0.00001
Beta-blocker	3.14%	8.93%	0.00000	9.51%	0.00001
Angiotensin	6.72%	22.5%	0.00000	21.61%	<0.00001
ARB	2.54%	12.5%	0.00000	13.54%	<0.00001
Other	3.66%	15.89%	0.00000	17.87%	<0.00001
Any	44.29%	90.36%	0.00000	92.22%	<0.00001

0 medications	55.71%	9.64%	0.00000	7.78%	<0.00001
1 medications	19.42%	24.11%	0.21013	23.05%	0.62722
2 medications	20.46%	31.96%	0.00040	32.56%	0.00811
3 medications	4.18%	23.93%	0.00000	24.78%	<0.00001
4 medications	0.22%	6.96%	0.00000	8.07%	<0.00001
Mean	0.74	2.05	0.00000	2.14	<0.00001

Control

There was an increase in blood pressure control in patients who remained in the programme (Table 3), however patients who stayed in the programme were more likely to have their BP under control upon enrolment. In the group of patients that did not have a second appointment (group A) the baseline BP control was 25% while in the other groups (B, C, D) was 34%, 36% and 43% respectively. These differences were statistically significant (Table 4). The BP control increased to 69% (95% CI 65%- 73%) in the individuals that visited at six months. In the patients that had the 12 month visit the control increased to 72% (95% CI 67%, 77%). Of patients who had both a six and 12-month follow-up appointment, the control increased to 77% (95% CI 72%-82%) at six months, but slightly decreased to 72% at 12 months (95% CI 66%-78%) (Table 3, Table 4).

DISCUSSION

Summary of results

Of the 1339 patients enrolled in ComHIP, only 552 (41%) had a follow up appointment at six months, and only 338 (25.2%) had a follow up appointment at twelve months. Participants who had more education, were older, had their hypertension under control at enrolment, or who had the opportunity to spend at least a year in the programme before the break in service were more likely to attend appointments at six and/or twelve months.

Among the group of patients who continued in the programme for six or twelve months, we found strong evidence of a reduction in DBP and SBP, and an increase (from under half to more than two thirds) of hypertension control. We also found strong evidence of an increase of the patients under treatment, of the number of medications received per patient, and a decrease in the number of individuals with severe hypertension.

Comparison with other studies

Other studies evaluating task sharing for hypertension management have shown modest levels of success. For example, one randomised controlled study conducted in Ghana using task sharing (but with supplying free medications) showed greater reductions in SBP in patients randomised to the arm that included trained nurses, as compared to the one that just provided free medications and health insurance [10].

The poor follow-up reported in our study is not unexpected. Many studies have shown poor levels of follow up or adherence to clinic appointments. In one study conducted in three primary care clinics in Kibera, Kenya between 2010 and 2012, 1465 hypertensive or diabetic patients were identified. Of these 31% of patients were lost to follow up. Of these 55% of non-diabetic patients had their BP under control by 24 months, but only 28% of diabetic patients [11].

In another study conducted in Kibera, Kenya between 2015 and 2016, 3861 hypertensive patients were identified in health centres or clinics. of those 3069 patients did not complete six months of follow up (79%). Of those patients who remained in the programme over 6 months, they found 63% adherence to appointments [12].

In a study conducted in the slums of Nairobi only 3.4% of participants showed completed compliance with the programme. 30% only showed up for one appointment, and 5% only had two visits. Similar to our study they found that patients who remained in the programme showed significant reductions in SBP and DBP [13].

In a study done in two sites (one rural and one urban) in Malawi, of 4075 patients referred for clinical care, only 61% attended their referral appointments. Of those 47% of hypertensive patients were still in contact after 24 months. Similar to our findings, they found uptake in care to be higher in older patients, being on anti-hypertensives prior to enrolment, and not being in employment. Unlike our study, they found that females were more likely to be retained in care .[14]

Similarly, a study of hypertensive and diabetic patients in rural Cameroon found that only 18.1% of participants were still in care after one year. However similar to our study they found significant decreases in SBP and DBP in hypertensive patients with at least two documented visits.

Strengths and Limitations

A major strength of this study is unlike most other hypertension programmes ComHIP uses existing GHS protocols and medications and does not require outside funds or intervention for medications. This means that there is a much greater chance of long term sustainability of the programme as it does not rely on outside sources for medications.

Limitations of the study include that data were only available for encounters with service providers within the ComHIP network. Any appointments with doctors, pharmacists (licensed or un-licensed) that were not part of ComHIP would not have been registered, so it is possible that patients were obtaining anti-hypertensives from non-licensed sellers, which would not be captured in the ComHIP database. Another limitation of ComHIP was that the cohort did not have a control.

Due to the extremely poor follow-up, it is not possible to generalise our findings regarding the impact on blood pressure control to other studies, other than to emphasize the importance of effective strategies to promote follow-up. Finally, it is important to remember that nearly 70% of the initial cohort was aware of their hypertension status and about half were taking medications, which is a much higher proportion than in the general population. While this was done in ComHIP to ensure access to hypertension management to community members who otherwise would not have been able to access services, it is an important consideration when considering generalisability to the overall population.

Interpretation

In the 25% of people who had a 12-month appointment, there was strong evidence of an increase of the patients receiving medications, the average number of medications received per patient, and the level of hypertension control, we also found a reduction in both BP and hypertension status. However, like most other studies in the region, the high loss to follow up highlights that innovative hypertension programmes such as ComHIP need to develop better ways to retain patients within the programme.

Community based hypertension programmes in resource poor setting often are complex to carry out, and are prone to poor follow-up. There are many possible reasons that follow up in our study was low.

The factor most associated with retention in the programme was enrolment date. This is significant as due to operational issues, there was gap of CommCare utilization for three months. Anecdotally FHI 360 ComHIP staff learned that this gap in CommCare service had caused both service providers and staff to believe that the intervention had stopped, which may have resulted in a low rate of completion of follow-up appointments. Considering difficulties associated with community based studies in low resource settings, it is imperative to ensure continuity of service. Other factors that could cause this association may be health care professional fatigue; engaging patients to present for appointments may require considerable effort, such as multiple phone calls and personal interaction, for which the CVD nurses did not receive additional monetary compensation. It is possible that over time, the enthusiasm of the CVD nurses for the intervention may have waned. Also, as in any low – resource settings, there is a great deal of workforce turnover, FHI 360 recognised this early in the implementation and trained extra staff to bridge the gaps, however it is still possible that new health care providers who replaced them may not have had the same level of training. A complementary component of the evaluation which includes qualitative research with different ComHIP stakeholders is underway to analyse in depth the possible reasons that may have caused people to not adhere to the programme. (see Adler et al Barriers and facilitators to the implementation of a community-based hypertension improvement project in Ghana: A qualitative study and Laar et al Health system challenges to hypertension and related non-communicable diseases prevention and treatment: perspectives from Ghanaian stakeholders)

Lastly, our study found that older individuals were more likely to continue in care, this was found in at least one other study[14] but was not reported on in most studies. This could be because older patients may have more time to attend clinics. Patients with their hypertension under control were about twice as likely to stay in the programme. This is not surprising as they had already exhibited better health seeking behaviours.

Recommendations:

For patients enrolled and who continued in the programme we found an important impact on the management of hypertension and in blood pressure control. However, the high loss to follow-up of patients recruited limits the potential public health impact of these types of programmes. In order to minimize the impact of externalities (such as the CommCare service gap in ComHIP) programmes should have standard procedures and back-up systems to maximize the possibility that patients stay in the programme, particularly younger and less educated individuals. Also, appropriate incentives should be put in place to keep programme staff fully engaged and avoid programme fatigue. Future studies should further identify causes of loss to follow-up and find effective ways to adapt programmes accordingly (e.g. access to treatment within the community, targeted behaviour change messaging) to ensure that most of patients recruited stay long term in the programme.

Acknowledgements
Funding for ComHIP was generously provided by the Novartis Foundation, Basel, Switzerland. We are grateful to all of cohort clients. We are also grateful to the leadership and political support of the Ghana Health Service (both from the national and district levels) for their support.

Competing interests
Co-authors PL, AKL, PP, AJA, and DP-M worked on the ComHIP Programme for which their institutions (LSHTM and UGSPH) have received grants from the Novartis Foundation. Co-authors RD, RD, and DM are staff of the FHI360, which provided technical direction to ComHIP implementation.

Authors' contributions
PL conceived of the project, PL and RD designed the interventions. PL, PP, AKL and AJA designed the research component of the project. DM, and RMMD supervised the implementation of the programme. RMMD is the programme data manager. AJA and DP-M performed the statistical analyses. AJA drafted the manuscript, with inputs from all authors. All authors read and approved the final version of the manuscript.

Consent to publish
Participants' consent was obtained for the purposes of publishing the results from the study. All the authors consented to the study results to be published in the form presented in the final version of this manuscript.

Data sharing
Summary statistics related to the dataset used in the project are available by request

Funding
Funds for the project was made available by Novartis Foundation, Basel, Switzerland. They did not have any input or control over this manuscript.

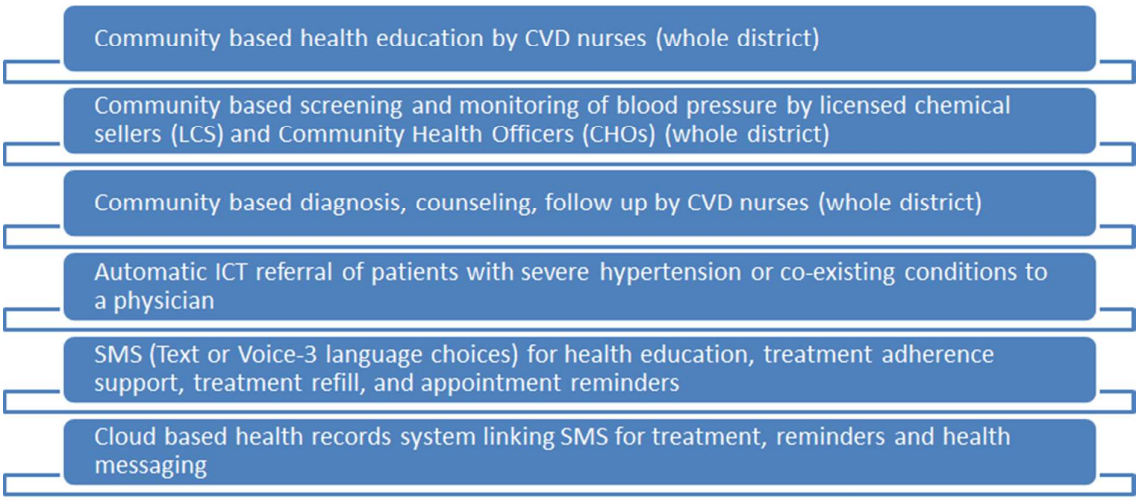
Figures

See attached supplementary file

REFERENCES

1. WHO, *World Health Organization-International Society of Hypertension Guidelines for the Management of Hypertension. Guidelines Subcommittee.* Am J Hypertens, 1999. **17**(2): p. 151–83.
2. Collaboration, B.P.L.T.T., *Effects of blood pressure lowering on cardiovascular risk according to baseline body-mass index: a meta-analysis of randomised trials.* The Lancet, 2015. **385**(9971): p. 867-874.
3. Collins, R., et al., *Blood pressure and coronary heart disease.* Lancet, 1990. **336**(8711): p. 370-1.
4. Law, M.R., J.K. Morris, and N.J. Wald, *Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies.* Bmj, 2009. **338**: p. b1665.

5. Olsen, M.H., et al., *A call to action and a lifecourse strategy to address the global burden of raised blood pressure on current and future generations: the Lancet Commission on hypertension.* Lancet, 2016. **388**(10060): p. 2665-2712.
6. Addo, J., L. Smeeth, and D.A. Leon, *Hypertension in sub-saharan Africa: a systematic review.* Hypertension, 2007. **50**(6): p. 1012-8.
7. Chow, C.K., et al., *Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries.* Jama, 2013. **310**(9): p. 959-68.
8. Lamptey, P., et al., *Evaluation of a community-based hypertension improvement program (ComHIP) in Ghana: data from a baseline survey.* BMC Public Health, 2017. **17**(1): p. 368.
9. GSS, *Population by Region, District, Locality of Residence, Age Groups and Sex, 2010. Accra, Ghana: Ghana Statistical Service.* http://www.statsghana.gov.gh/docfiles/population_by_region_district_locality_of_residence_age_groups_and_sex,_2010.pdf. *Accessed November 22, 2016* 2012.
10. Ogedegbe, G., 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**(5): p. e1002561.
11. Sobry, A., et al., *Caseload, management and treatment outcomes of patients with hypertension and/or diabetes mellitus in a primary health care programme in an informal setting.* Trop Med Int Health, 2014. **19**(1): p. 47-57.
12. Kuria, N., et al., *Compliance to follow up and adherence to medication in hypertensive patients in an urban informal settlement in Kenya: comparison of three models of care.* Trop Med Int Health, 2018.
13. Werner, M.E., et al., *Results of a hypertension and diabetes treatment program in the slums of Nairobi: a retrospective cohort study.* BMC Health Services Research, 2015. **15**: p. 512.
14. Musicha, C., et al., *Accessing clinical services and retention in care following screening for hypertension and diabetes among Malawian adults: an urban/rural comparison.* J Hypertens, 2016. **34**(11): p. 2172-9.



Supplementary figure 1) components of the ComHIP Programme

Visit Number	When?	Activity
1	After patient has been screened and referred by LCS, CHO	CVD Nurse to recheck BP
2	Two weeks after visit 1	1. CVD Nurse to recheck BP and confirm diagnosis 2. Enroll patient, perform risk assessment, perform anthropometric measurements 3. Refer to *Referral SOP for CVD nurse* for all patients that should be referred to Physician. 4. Initiate treatment 5. Order laboratory investigation as needed 6. Perform Hypertension counseling
3	6 weeks after visit 2	1. Re-check BP 2. Assess treatment, perform counseling
4	6 weeks after visit 3	1. Review treatment plan until goal is reached 2. Perform anthropometric measurements every 3 months after enrollment
5 & subsequent visits	• Every 3 months for patients with Mild Hypertension (treated by CVD nurse) • Every 2 months for patient with Moderate Hypertension (treated by CVD nurse) • Monthly for Patients with High (treated by Physicians only)	1. Re-check BP, review treatment, assess for risk factors, perform Hypertension counseling 2. Conduct follow up assessment every 6 months after enrollment

Supplementary Figure 2. guidelines for patient visits

Phase	Activity	Community Health Officer	Licensed Chemical Seller	CVD Nurse	Physician
Phase 1: Screening	Community BP screening	Yes	Yes	No	No
	Screening referral	Yes	Yes	No	No
Phase 2: Diagnostic Evaluation	Confirmation of BP (HTN) diagnosis	No	No	Yes	Yes
	Staging of degree of HTN	No	No	Yes	Yes
	Assessment of other CVD risk factors	No	No	Yes	Yes
	Assessment of prevailing CVD symptoms	No	No	Yes	Yes
	Overall risk assessment/ Stratification	No	No	Yes	Yes
	Assessment of family history of CVD	No	No	Yes	Yes
	Laboratory investigation	No	No	Yes	Yes
	Assessment of target organ complication	No	No	Yes	Yes
	Assessment of Lifestyle Issues	No	No	Yes	Yes
	Diagnostic referral	No	No	Yes	No
	Baseline Anthropometry	No	No	Yes	Yes
Phase 3: Management, Monitoring & Follow Up	Recommendation for drug treatment	No	No	Yes	Yes
	Medication Dispensing	No	Yes	No	No
	Recommendation for Non-drug treatment	Yes	Yes	Yes	Yes
	Evaluation of drug side effects	No	Yes	Yes	Yes
	Monitoring of BP response to treatment	No	Yes	Yes	Yes
	Adherence Counselling	No	Yes	Yes	Yes
	Anthropometric monitoring	No	No	Yes	Yes
	Regular follow up and interaction	No	No	Yes	No
	Management referral	No	No	Yes	Yes*

Supplementary Table 1) Summary of roles of various service delivery personnel
*In rare instances, certain patients may be referred by the Physician to a hypertension specialist

I. Diuretic: Bendroflumethiazide. –initial dose, 2.5mg daily. Maximum dose of 5mg daily.

II. Beta-blocker: Atenolol-initial dose of 50mg daily. Maximum dose of 100mg daily provided the heart rate is greater than 60/min on the lower dose.

III. Calcium channel blocker: Nifedipine retarde or XL -initial dose 30mg daily. Maximum dose of 60 to 90 mg daily.

Supplementary Table 2) Recommended medications and dosages

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	7
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-8
		(b) Give reasons for non-participation at each stage	7-8
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7-9
		(b) Indicate number of participants with missing data for each variable of interest	7-9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7-9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	10-13
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Results from an innovative model of hypertension care: The ComHIP Cohort study

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026799.R1
Article Type:	Research
Date Submitted by the Author:	03-Jan-2019
Complete List of Authors:	Adler, Alma; London School of Hygiene & Tropical Medicine, Department of Non-communicable Disease Epidemiology; Harvard Medical School Laar, Amos; School of Public Health, University of Ghana, Department of Population, Family & Reproductive Health Prieto-Merino, David; London School of Hygiene and Tropical Medicine, Department of Non-communicable Disease Epidemiology Der, Reina; Family Health International Mangortey, Debbie ; Family Health International Dirks, Rebecca; Family Health International Lamptey, Peter; London School of Hygiene & Tropical Medicine, Department of Non-communicable Disease Epidemiology Perel, Pablo; London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology
Primary Subject Heading:	Global health
Secondary Subject Heading:	Epidemiology, Public health
Keywords:	Hypertension < CARDIOLOGY, cohort, EPIDEMIOLOGY

Results from an innovative model of hypertension care: The ComHIP Cohort study

Alma J Adler[12*], Amos K Laar[3*], David Prieto-Merino[1], Reina M. M. Der[4], Debbie Mangortey[4], Rebecca Dirks[5], Peter Lamptey[1], Pablo Perel[1]

***Co-first authors**

Correspondence:
Dr. Alma J Adler
alma.adler@lshtm.ac.uk

[1]Department of Non-communicable Disease Epidemiology. London School of Hygiene & Tropical Medicine. Keppel St, London. WC1E 7HT

[2]Department of Global Health and Social Medicine, Harvard Medical School. Boston, MA, United States

[3]Department of Population, Family, & Reproductive Health, School of Public Health, University of Ghana, LG 13, Legon, Accra, Ghana.

[4]Family Health International 360, Accra, Ghana

[5]Family Health International 360, Washington DC, United States.

Alma J Adler alma.adler@lshtm.ac.uk
Amos K Laar alaar@ug.edu.gh
David Prieto -Merino david.prieto@lshtm.ac.uk
Reina M. M. Der RDer@fhi360.org
Debbie Mangortey DMangortey@fhi360.org
Rebecca Dirks rdirks@fhi360.org
Peter Lamptey plamptey@fhi360.org
Pablo Perel pablo.perel@lshtm.ac.uk

Word count: 4435

Abstract:

Objectives: to evaluate the effectiveness of the Community-Based Hypertension Improvement Project (ComHIP) in increasing hypertension control.

Setting: Lower Manya Krobo, Eastern Region, Ghana.

Participants: All adult hypertensive community members, except pregnant women, were eligible for inclusion in the study. We enrolled 1339 participants, 69% of which were female. 552 had a six-month visit, and 338 had a 12-month visit.

Interventions: We report on a package of interventions where community based CVD nurses were trained by Family Health International (FHI360). CVD nurses confirmed diagnoses of known hypertensives and newly screened individuals. Participants were treated according to clinical guidelines established through the project's Technical Steering Committee. Patients received three types of reminder and adherence messages. We used CommCare, a cloud based system, as a case management and referral tool.

Primary outcome: Hypertension control defined as blood pressure under 140/90 mm Hg. Secondary outcomes: Changes in blood pressure and knowledge of risk factors for hypertension.

Results: After one year of intervention 72% (95% CI 67%, 77%) of participants had their hypertension under control. Systolic BP was reduced by -12.2 mmHg (95%CI 14.4, -10.1) and diastolic BP by -7.5 mmHg (95%CI 9.9, 6.1). Due to low retention, we were unable to look at knowledge of risk factors. Factors associated with remaining in the programme for 12-months included education, older age, hypertension under control at enrollment, and enrollment date. The majority of patients who remained in the programme were on treatment, with two-thirds taking at least two medications.

Conclusions: Patients retained in ComHIP had increased BP control. However, high loss to follow-up limits potential public health impact of these types of programmes. To minimize impact of externalities, programmes should include standard procedures and back-up systems to maximize the possibility that patients stay in the programme.

Keywords:

Hypertension, Ghana, Community based cohort study.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ComHIP is a large cohort study testing a community based model of hypertension care
- Trained community based cardiovascular nurses conducted screening, diagnosis and management of hypertension patients
- Patients were sent three types of SMS, daily reminders to take their medications, appointment reminders, and weekly health education messages
- Protocol stated that blood pressure would be checked with a minimum of three serial readings at regular intervals, but at a minimum of 6-monthly intervals
- a limitation of the study was that it did not include a control group

INTRODUCTION:

Globally, raised systolic blood pressure (SBP) is one of the greatest risk factors for disability (GBD, 2017). Hypertension is generally considered to be the level of raised blood pressure (BP) where medications show a reduction in clinical events in randomized trials. This is generally accepted as ≥140 SBP mmHg or ≥90 diastolic mmHg (DBP)[1].

Evidence shows that lowering hypertensive individual's blood pressure with anti-hypertensive drugs reduces the risk of further cardiovascular events; with a reduction in stroke by an estimated 35–40% and a myocardial infarction and heart failure reduced by 20–25% reduction [2-4]. Whilst average age-standardised BP is decreasing in most high-income countries, it is increasing in most low and middle income countries (LMICs) [5] with 32% to 50% of adults estimated to be hypertensive in sub-Saharan Africa [6].

The Prospective Urban Rural Epidemiology (PURE) study showed that despite high levels of hypertension worldwide, only 34% of Africans are aware of their hypertension status, only 31.3% receive any treatment and only 6.5% have their blood pressure under control .[7] Our recent study of hypertension prevalence in the Lower Manya Krobo, Ghana, showed that only 2.1% of hypertensives had their blood pressure under control [8].

Because of the great burden of hypertension in Sub-Saharan Africa and the poor rate of hypertension control, innovative methods for hypertension management are needed. Launched in 2015, the Community-Based Hypertension Improvement Project (ComHIP) introduced an innovative model for hypertension control at the community level. ComHIP is a public-private partnership between the Ghana Health Service, FHI 360 and the Novartis Foundation.

The aim of ComHIP is to improve hypertension management and control in the Lower Manya Krobo district in the Eastern Region of Ghana. The programme includes a package of interventions composed of six components (Supplementary Figure 1), aimed at increasing access to hypertension services at the community level. Screening in the community is provided by Cardiovascular Disease (CVD) nurses and Community Health Officers (CHOs), as well as through local private sector drug shops called licensed chemical sellers (LCS). Ongoing hypertension management is provided by CVD nurses or, for those with co-morbidities or severe conditions, at district hospitals. Patients are encouraged to routinely monitor their blood pressure by having their BP measured at a LCS. The various service providers are linked through a cloud-based system which revolve around bringing hypertension care into the community. Physicians, Community based CVD nurses, CHOs, and LCS staff were trained by FHI 360 to provide specific services.

For instance, CVD nurses conduct hypertension screening, and confirmation of hypertension diagnosis, staging of degree of hypertension, assessment of other CVD risk factors, counselling, monitoring and follow up and trained LCS conduct community BP screening and awareness raising. Further information is found in the supplementary material.

The ComHIP Programme is being independently evaluated by the University of Ghana School of Public Health and the London School of Hygiene & Tropical Medicine with a mixed method approach through a series of quantitative and qualitative studies. These studies include repeat cross-sectional surveys within the intervention and comparison districts to track overall awareness and prevalence of hypertension; a cohort of hypertensive persons included in ComHIP to assess hypertension control; a cost-effectiveness evaluation; a study to assess the level of patient-centeredness within the

programme; and a qualitative assessment of ComHIP stakeholders. In this paper we report the results of the cohort study.

Objectives

The objective of this study was to evaluate the effectiveness of ComHIP for controlling hypertension in hypertensive patients enrolled into the ComHIP programme.

METHODS:

Study design

The study was a prospective cohort study which included all patients recruited into the ComHIP Programme.

Setting

The study was conducted in Lower Manya Krobo, a municipality in the Eastern region of Ghana. This is a peri-urban setting approximately two hours from the national capital, Accra with a population of approximately 89,246, of whom 84% live in urban areas.[9] Recruitment began October 2015 and ended in December 2016.

Training

FHI360 and the MoH conducted training. Training duration ranged from three days for LCS, and physicians to 6 days for CVD nurses. Aside from the general training package (BP screening including the recommended standard operating procedures for BP checking, Lifestyle modification counselling, interviewing/counselling techniques, treatment adherence counselling) offered to all personnel, CVD nurses and physicians received additional training on hypertension diagnosis, assessing the risk of patients. Assessing for TODs, drugs for the management of hypertension and their side effects and contraindications.

Participants were issued certificate of participation signed by the cardiologist specialist who conducted the training and the director general of the GHS. Also, as is done by the GHS the continuous learning log books of the GHS personnel were endorsed by the project to document the training received.

Participants

Patients were enrolled into the programme if 1) they were known hypertensives or 2) had an elevated blood pressure reading at any ComHIP screening. Any individual living in Lower Manya Krobo 18 years or older was eligible, except pregnant women. Patients had to have access to a mobile phone to be enrolled in the programme. However, in order to negate loss of patients, patients without phones were not necessarily excluded based on this, rather, they were encouraged to provide phone numbers of a willing third party who lived nearby.

Intervention

Community members were screened by CHOs, LCS, or CVD nurses, using Omron M6 BP monitors that came with a cuff size of 42 cm which is about the 2nd largest cuff size in the market for those machines. Though the project requested for nurses to report cases of patient with bigger upper arms that required bigger cuff sizes, throughout the implementation, no such reports was received. The average of three serial readings was used to confirm hypertension diagnosis. Patients who were at risk of hypertension (SBP ≥120, but <140) were given health education. All patients with SBP≥140 or DBP ≥90 were referred to a CVD nurse for diagnosis. Patients with SBP ≥180 or DBP ≥110 were enrolled and referred to the physician for urgent care. Patients that were considered to have severe hypertension, (SBP ≥180 or DBP ≥110 or SBP between 160 – 179 or DBP 100 – 109 with one or more risk factors, or any evidence of organ damage see Appendix A) were referred for management by a physician at one of the district hospitals, until their blood pressure was stable, and then they were returned to CVD nurses for care. All other patients were managed by CVD nurses.

Hypertensive individuals were enrolled and followed for at least one year. All patient interactions (with LCS, CHOs, CVD nurses, community and hospital pharmacist and doctors) were recorded and uploaded through the CommCare platform. Patients were requested to present for appointments at the following intervals; monthly BP monitoring appointments, monthly, bi-monthly or quarterly review visits (depending on risk factors and personal factors); and six-monthly follow up assessments. Participants were recruited from October 2015 until December 2016, and followed through December 2017. Guidelines for patient visits can be found in the supplementary materials (Supplementary Table 1 and Supplementary Figure 2, Appendix A).

All enrolled participants were treated based on the same clinical guidelines established through the project's Technical Steering Committee, which included senior members of the GHS. The treatment goal was to improve blood pressure of all patients to below 140/90 mmHg. Participants were initiated onto drug therapy and supplemented with non-drug therapy (lifestyle modification including low salt diets, increased fruit and vegetable diet, reduction in alcohol consumption, smoking cessation and regular aerobic exercise) irrespective of their risk level. The decision to initiate a monotherapy or multiple drug therapy depended largely on the level at which the participants BP was above goal and the overall risk level of patients. Recommended drugs and dosages are found in supplementary Table 2. Patient's response to antihypertensive were reviewed every three months if possible and modified based on recommended guidelines if required. In Ghana, there is a system of National Health Insurance, and every Ghanaian is required to enrol in. The Scheme provides select medications at no cost for anyone who has a valid National Health Insurance card. Although the NHIS does not attempt to treat all diseases suffered by insured members, over 95% of disease conditions that afflict us are covered by the NHIS. Services can be accessed at accredited health facilities.

CommCare is a vital component of ComHIP. It serves as a case management system, referral tool, and job aid for providers. The CommCare database is linked with a SMS platform to automatically send daily adherence reminders, weekly healthy living tips, and consultation and prescription refill reminders to enrolled patients. These messages are sent via text or voice SMS with four language choices. The programme is described in more detail elsewhere [8]. Briefly, through CommCare patients diagnosed with severe hypertension or co-existing conditions are automatically referred to a physician. All patients enrolled in ComHIP receive SMS daily for medication reminders, weekly for health education, and upon need for appointment and screening reminders. CommCare also provides a cloud based health records system that links patients' records with the SMS system. The SMS

component of the project was implemented by a third party Viamo, to facilitate the link between the two systems a bridge was built to automatically relay relevant information from the projects cloud-based health records to the Viamo messaging platform. To ensure confidentiality, only information relevant to schedule appoints is relayed to the Viamo platform (i.e. patient code, date of visit, type of visit, next review or refill appoint, patient's phone number, preferred, language, time of receipt of message and format of message, referral details and BP). When a visit is missed, the system, automatically relays back to the CVD nurse who enrolled the Patient or is managing the Patient via text message for the nurse to trace the patient. Due to operational problems, there was a break in service in CommCare that began on 12 May 2016 for a period of at least three months.

Variables

Main outcomes:

The main outcomes of interest were hypertension control (<140/90 mmHg), and changes in systolic and diastolic blood pressure. Because of the low follow up rate, we also used appointment around six months, and appointment around 12 months as outcomes of interest.

Other variables:

Other variables included knowledge of risk factors for hypertension, demographic factors including age, gender and marital status; risk factors such as body -mass index (BMI), awareness of hypertension (defined as having knowledge of a previous diagnosis of hypertension), having hypertension under control prior to enrolment, and having previous diagnoses of other heart diseases, and socioeconomic factors. A full list of variables is found in Table 1.

Data collection

Data were collected on blood pressure using standardised protocols. At six and 12 months forms were administered by health care providers to collect information on patient knowledge of risk factors for hypertension and health behaviours.

All data were collected and downloaded from the CommCare platform. Initially data was intended to be analysed from the patient knowledge/behaviour forms used at six-month and 12-month follow up appointments. Due to poor levels of follow up, any appointment between five and seven months after enrolment was used for the six-month appointment analysis, and any appointment between 11 and 13 months after enrolment was used for the 12-month appointment analysis.

Sample size

This cohort study included all the patients recruited in the ComHIP programme and a specific sample size was not calculated. However, in the protocol we assumed that the total district population is about 90,000; about 30,000, of whom are adults, and about 36% [12000] are estimated to be hypertensive. Assuming that about 10% of the adults with hypertension in the district will be included in the ComHIP Programme we would have a cohort of 1,200 hypertensive patients.

We estimated that a cohort study of 1200 hypertensive patients would provide a power greater than 90% (with an alpha error of 0.05) to detect a two-fold increase of control of hypertension (from 4% to 8%).

Patient and Public Involvement

Community members, including community leaders, were first involved through a stakeholder workshop. In this workshop, community members shared their thoughts, knowledge, and concerns about health in general, NCD-related conditions, and access to healthcare. Furthermore, community members were made aware of the hypertension project planned to be initiated in their community. This information was considered in finalizing the design of the service delivery model and the development of prevention, education, and behaviour change messages.

Patients were recruited into the project through free screening offered at 1) local drug shops, names Licensed Chemical Sellers; 2) Community Health Planning Service (CHPS) sites; or 3) Community pharmacies. There were community screening activities and radio programs through which community members were educated on the project and hypertension in general. In addition, ComHIP staff conducted annual stakeholder meetings to provide updates to community members on the project progress.

Statistical methods

We recoded exposures to reduce the number of levels and of missing values: For all the previous diagnosis / awareness: We have coded "missing" or "not known" or "no answer" as 0, so that value 1 always means "Patient knows of a previous diagnosis" while value 0 means anything else (patient does not know or answer is missing). Because there were few previous diagnoses of each specific event (MI, stroke, diabetes…) we created a variable with value 1 if any diagnosis was present and 0 if none was present.

For education, we assumed that those that did not know (48) or did not respond (26) did not have previous formal education (the largest group). We then grouped education in 4 levels: 1) no formal education, 2) primary (completed or not) 3) secondary (completed or not) and 4) higher (university)

For marital status, we made 4 categories: 1) Never married 2) married or cohabiting 3) separated or divorced 4) widowed.

We described the distribution of each variable at baseline, six-months and 12-months follow up, although comparisons cannot be done directly due to the large number of individuals that did not have follow up. To study what variables might affect the patient staying for 12-months in the programme we ran a logistics regression for the binary outcome variable: "patient had 12-month visit (Y/N)".To consider the loss to follow up (patterns of visits), we separated the individuals into four different groups: (A) those individuals that did not come to any follow up visit, (B) those that came only to the 6-month visit, (C) those that came only to the 12-month visit, and (D) those that came to both follow up visits.

We described the absolute values of blood pressure (SBP and DBP), the proportion of patients with blood pressure under control and the distribution of hypertension stages for each of these groups in each of the visits. We estimated the average changes of blood pressure for each group at each follow up visit and we compared the changes between groups with Student's t-tests. We compared the mean of SBP and DBP between the groups with ANOVA models. To compare the proportion of patients with HT control or the distribution of hypertension stages between groups we used chi-square tests. To test the changes of variables within groups we used paired t-tests for continuous variables and marginal homogeneity tests for categorical variables.

Ethical Approval

Ethical approval was granted by the Institutional Review Boards (IRBs) of LSHTM (LSHTM Ethics Ref: 10,152), the Ghana Health Service (ID NO. GHS-ERC 04/01/15), and the University of Ghana at Noguchi Memorial Institute for Medical Research (Ethics clearance # IRB00001276). Written informed consent was obtained from all participants.

RESULTS:

Participants:

A total of 18,339 individuals 18 years and over were screened , 4118 referred to CVD nurses to confirm diagnosis, and of those 1339 were enrolled (76 (5.7%) low risk Grade 1 BP which is SBP 140 – 159 or DBP 90 – 99 without any target organ damages (TODs), co-morbidities or ≥ 2 risk factors), 559 (41.7%) (Moderate risk (SBP 160-179 or DBP 100 – 109 without any TODs, co-morbidities or ≥ 2 risk factors or Grade 1 BP with TODs, co-morbidities or ≥ 2 risk factors), and 704 (52.6%) High risk (Grade 3 which is SBP ≥ 180 or DBP ≥ 101 without any TODs, co-morbidities or ≥ 2 risk factors or Grade 2 BP with TODs, co-morbidities or ≥ 2 risk factors).

General characteristics of the cohort

The average age of the cohort was 58 years. Everyone was enrolled into the cohort by CVD nurses. Of the 1,339 people enrolled in the cohort, 24% were referred to ComHIP by LCS, 45% were referred by CHO, 23% were referred by CVD nurses, 3% were through physicians, and 5% were referred through other channels. 69% of the cohort was female, 31% male. Other characteristics of people enrolled in the cohort are found in Table 1.

Table 1. Characteristics of participants in the study at baseline.

Characteristic	% all	% 6 months	%12 months
Number	1339	552	338
Referred by			
LCS	23.9	23.4	24.3
CHO	45.0	40.8	38.5
CVD Nurse	23.3	25.4	26.9
Other	7.8	10.5	10.4
Sex			
Male	30.8	32.3	30.7
Female	69.2	67.8	69.3
Age class			
30-44	17.9	14.7	13.6
45-54	23.5	21.7	24.3
55-64	27.3	31.9	32.0
65+	31.4	31.7	30.2
Hypertension stage			
Normal	26.4	38.6	41.7
Stage I	39	39.9	39.4
Stage II	19.6	14.5	13.0

Stage III	14.9	7.1	5.9
Mean BP			
DBP	90.8	87.6	86.9
SBP	149.0	143.3	141.2
Education			
No formal education	37.0	32.3	31.4
Primary	41.7	431	45.6
Secondary	16.1	18.5	14.8
Higher	5.2	6.2	8.3
Ethnicity			
Akan	4.2	28.6	21.4
Dangme	69.5	42.2	26
Ewe	22	39.3	22.4
Other or don't know	4.3		
Religion			
Christian	96	97.6	97.9
Muslim	3.2	1.5	1.2
Traditional	0.5	0.4	0.3
None	0.3	0.5	0.6
Marital status			
Never married	5.7	5.1	3.6
Married/Cohabiting	54.4	54.7	57.7
Separated/Divorced	5.5	14.1	15.4
Widowed	26.1	25.9	23.1
No response	0.2	0.2	0.3
Household income			
Less than 728 GHC	18.7	17.0	17.2
728-1020 GHC	17.4	20.8	19.8
1021-1098	6.4	5.3	6.5
1099-1263	5.0	4.9	4.7
More than 1263 GHC	12.3	11.1	11.8
Don't know/no response	40.2	40.9	39.9
Aware of hypertension status			
Never had BP measured	18.7	17.6	16.3
Was not aware	12.9	11.4	10.7
Aware	68.5	70.8	73.1
Taking treatment			
Never diagnosed	31.5	29.2	26.9
Diagnosed and no treatment	18	15.0	16.0
Treatment	50.3	55.6	56.8
Don't know	0.2	0.2	0.3
BMI			
Underweight (BMI <18.5)	5.4	4.9	5.0
Normal weight (BMI 18.5-24.9)	43.7	44.8	43.2
Overweight (BMI 25-29.9)	29.2	30.1	32.5
Obese (BMI 30+)	21.7	20.3	19.2

*All hypertensive patients enrolled in cohort

**Hypertensive patients with six-month appointment/follow up

**Hypertensive patients with a twelve-month appointment/follow up

Other risk factors:

5.4% of the sample was underweight, 43.7% was normal, 29.2% was overweight and 21.7% was obese. The mean BMI at enrolment in the cohort was 26.1 (95% CI 25.82, 26.4).

We did not analyse smoking, cholesterol or diabetes as only 1% of the sample were smokers, 3.5% reported having had a previous cholesterol test, and only 28% had a previous diabetes test.

Blood Pressure at enrolment

The average SBP was 147.2 (SD 22.1) mmHg, and average DBP was 89.9 (SD 13.3) mmHg. At enrolment 917 (68.5%) had a previous diagnosis of hypertension, of which 654 (71.3%) were already taking some anti-hypertensives, and 297 (32.4%) had their blood pressure under control.

Blood pressure management

Of the 1339 enrolled in the study, 712 (53.2%) did not come for a follow up (group A), 289 (21.6%) had only a six-month visit (group B), 75 (5.6%) had only the 12-month visit (group C) and 263 (19.6%) had both visits (group D). In total only 552 (41%) had a six month follow up appointment, and only 338 (25%) had a 12 month follow up appointment.

Loss to follow up and Characteristics of those who stayed in the study

Patients with their hypertension already under control were more likely to present for care. The variable that showed the greatest association with likelihood of having a six or twelve-month appointment was enrolment month. Participants who enrolled earlier were much more likely to stay in the programme than those who enrolled later (Table 1)

Multivariate analysis suggested that recruitment before 12 May 2016 (one year before the break in service), age, education and hypertension under control in the first visit showed significant associations with having a twelve-month appointment. Recruitment after 12 May 2016 reduced the chances of coming to further visits, the older the patient and the higher the education level, the higher the chances that the patient would come to the follow up visits. Patients with controlled HT at enrolment were nearly twice as likely to come to follow up visits. None of the other variables showed significant associations (Table 2).

Table 2) multivariate analysis of baseline characteristics associated with staying in the programme 12 months

	OR	95% CI	P value
Enrolled year prior to break	0.46	(0.35, 0.60)	**0.00**
Sex	0.88	(0.63, 1.24)	0.48
Age (one year increments)	1.01	(1.00, 1.02)	**0.03**
BMI	1.00	(0.97, 1.02)	0.90
Edu. reference category: no formal education			
Primary education	1.41	(1.03, 1.93)	**0.03**
Secondary Education	1.13	(0.73, 1.73)	0.59
Higher education	2.42	(1.33, 4.43)	**0.004**
Reference cat: Never married			
Married/cohabitating	1.77	(0.90, 3.48)	0.10
Separated/Divorced	1.86	(0.90, 3.87)	0.10
Widowed	1.27	(0.61, 2.64)	0.52
Household size	1.01	(0.95, 1.07)	0.69
Hypertension control	1.93	(1.47, 2.54)	**<0.001**
Awareness of hypertension	1.00	(1.00, 1.00)	0.97
Hypertension treatment	1.00	(0.99, 1.00)	0.33
Any other previous diagnosis	0.86	(0.69, 1.07)	0.18
Confidence in management of hypertension	1.00	(1.00, 1.01)	0.63

Changes in Blood Pressure

Because 12 month follow up was below 30%, we did not look at overall changes in blood pressure, but we did look at overall changes in blood pressure in those that remained in the study at six and twelve months.

On average, patients who enrolled and presented for a follow-up appointment at around six months had a 10.3 mmHg reduction in SBP (95% CI -12.0,-8.6) and a 6.3mmHg reduction in DBP (95% CI -7.2, -5.2) (Table 3). There was a greater reduction in those patients who had a follow up appointment at one year, when there was a 12.2 mmHg reduction (95% CI -14.4, -10.1) in SBP and a 7.5 mmHg (95% CI 9.9, 6.1) reduction in DBP after one year in the programme. Not all patients who had a 12 month appointment also had a six month appointment, 263 had both, and they had am 11.9 mmHg reduction (95% CI -14.3, -9.5) in SBP and 7.1 reduction (95% CI -8.6, -5.5) in DBP (Table 3).

Knowledge of risk factors

Because of the poor retention, we were unable to comment on knowledge or risk factors.

Table-3) Changes in BP means and hypertension control by patterns of visits.

Groups	N	Vis.	SBP		DBP		HT Control
			Mean (SE)	Mean dif. (95%CI)	Mean (SE)	Mean dif. (95%CI)	% (95% CI)
All patients	1339	E	147.2 (0.60)		89.9 (0.36)		31% [29% , 34%]
	552	6m	132.9 (0.80)	-10.3 [-12.0 , -8.6]	81.3 (0.47)	-6.3 [-7.3 , -5.2]	69% [65% , 73%]
	338	12m	128.9 (1.05)	-12.2 [-14.4 , -10.1]	79.4 (0.61)	-7.5 [-8.9 , -6.1]	72% [67%, 77%]
(A) No visits	712	E	150.4 (0.85)		91.7 (0.49)		25% [21% , 28%]
(B) Only 6m	289	E	146.4 (1.28)		89.0 (0.77)		34% [29% , 40%]
		6m	135.7 (1.15)	-10.1 [-13.2 , -8.1]	82.7 (0.68)	-6.3 [-7.8 , -4.8]	61% [55% , 67%]*
(C) Only 12m	75	E	145.9 (2.62)		90.2 (1.63)		36% [25% , 48%]
		12m	132.5 (2.56)	-13.5 [-18.5 , -8.6]	81.0 (1.38)	-9.2 [-12.4 , -6.0]	71% [59% , 81%]*
(D) 6 & 12m	263	E	139.8 (1.18)		86.1 (0.80)		43% [37% , 50%]
		6m	129.8 (1.08)	-10.0 [-12.2 , -7.7]	79.8 (0.63)	-6.3 [-7.8 , -4.8]	77% [72% , 82%]*
		12m	127.9 (1.13)	-11.9 [-14.3 , -9.5]	79.0 (0.67)	-7.1 [-8.6 , -5.5]	72% [66% , 78%]*

* The comparison of these intervals with enrolment visit of the same group produce all p-values <0.0001

E= enrolment

There was also a significant reduction in hypertension stage, with a lower percentage of hypertensive individuals having stage III hypertension over time (Table 4).

Table 4) Distribution of Hypertension Stage in each group in each visit.

The P-values are extracted from: (1) Chi-square tests to compare that row with group A of no follow-up. (2) from marginal homogeneity tests comparing the distribution of the same group in enrolment visit.

Groups by patterns of visits	N	Visit	No HT	Stage I	Stage II	Stage III	P-value
All patients	1,339	1m	31.0%	39.0%	18.4%	11.6%	
	552	6m	68.7%	19.7%	9.4%	2.2%	< 0.001 (2)
	338	12m	71.9%	19.5%	6.5%	2.1%	< 0.001 (2)
(A) No follow-up	712	1m	24.6%	38.7%	21.5%	15.2%	
(B) Only 6m visit	289	1m	34.3%	39.4%	17.0%	9.3%	0.002 (1)
	289	6m	60.9%	24.2%	12.1%	2.8%	<0.001 (2)
(C) Only 12m visit	75	1m	36.0%	36.0%	17.3%	10.7%	0.167 (1)
	75	12m	70.7%	14.7%	10.7%	4.0%	< 0.001 (2)
(D) 6 & 12m visit	263	1m	43.4%	40.3%	11.8%	4.5%	<0.001 (1)

	263	6m	77.2%	14.8%	6.5%	2.2%	< 0.001 (2)
	263	12m	72.3%	20.9%	5.3%	1.5%	< 0.001 (2)

Awareness

Overall awareness of hypertension status in the overall cohort was 68.5% at enrolment. Individuals who stayed in the programme longer, were more likely to be aware of their hypertension status. 70.8% of individuals who stayed in the programme for six months were aware of their hypertension status, and 73.1% of those who stayed in the programme for 12 months were aware of their hypertension status (Table 1).

Treatment

Treatment increased between enrolment and six and twelve-month appointments. Although only 44.2% of patients were receiving any medication at enrolment, the majority were being treated at six months (90.4%) and at 12 months (92.2%). At enrolment, the majority of patients who were on treatment were taking a calcium channel blocker (CCB) (36% of all patients), but at six months the majority were on diuretics (75.9%) followed by a CCB (69.5%). The same pattern was found at 12 months with 79.8% taking diuretics, and 71.5% taking a CCB (Table 5)

In patients who had a six-month appointment, 24.1% were taking only one medication, 32% were taking two medications, and over 30% were taking more than two medications. In patients who had a 12-month appointment, 23 % were taking one medication, 32.6% were taking two medications, and over 32% were taking more than two medications.

Table 5) treatment pattern in the cohort at enrolment, six months and 12 months with p-values for differences.

Treat	Enrolment	6 month	P change	12 months	P change
Diuretic	21.66%	75.89%	0.00000	79.83%	<0.00001
Calcium CB	36.07%	69.46%	0.00000	71.47%	<0.00001
Beta-blocker	3.14%	8.93%	0.00000	9.51%	0.00001
ACE inhibitor	6.72%	22.5%	0.00000	21.61%	<0.00001
ARB	2.54%	12.5%	0.00000	13.54%	<0.00001
Other	3.66%	15.89%	0.00000	17.87%	<0.00001
Any	44.29%	90.36%	0.00000	92.22%	<0.00001

0 medications	55.71%	9.64%	0.00000	7.78%	<0.00001
1 medications	19.42%	24.11%	0.21013	23.05%	0.62722
2 medications	20.46%	31.96%	0.00040	32.56%	0.00811
3 medications	4.18%	23.93%	0.00000	24.78%	<0.00001
4 medications	0.22%	6.96%	0.00000	8.07%	<0.00001
Mean	0.74	2.05	0.00000	2.14	<0.00001

Control

There was an increase in blood pressure control in patients who remained in the programme (Table 3), however patients who stayed in the programme were more likely to have their BP under control upon enrolment. In the group of patients that did not have a second appointment (group A) the baseline BP control was 25% while in the other groups (B, C, D) was 34%, 36% and 43% respectively. These differences were statistically significant (Table 4). The BP control increased to 69% (95% CI 65%-73%) in the individuals that visited at six months. In the patients that had the 12 month visit the control increased to 72% (95% CI 67%, 77%). Of patients who had both a six and 12-month follow-up appointment, the control increased to 77% (95% CI 72%-82%) at six months, but slightly decreased to 72% at 12 months (95% CI 66%-78%) (Table 3, Table 4).

DISCUSSION

Summary of results

Of the 1339 patients enrolled in ComHIP, only 552 (41%) had a follow up appointment at six months, and only 338 (25.2%) had a follow up appointment at twelve months, and 263 (20%) had both six and 12 month appointments Participants who had more education, were older, had their hypertension under control at enrolment, or who had the opportunity to spend at least a year in the programme before the break in service were more likely to attend appointments at six and/or twelve months.

Among the group of patients who continued in the programme for six or twelve months, we found strong evidence of a reduction in DBP and SBP, and an increase (from under half to more than two thirds) of hypertension control. We also found strong evidence of an increase of the patients under treatment, of the number of medications received per patient, and a decrease in the number of individuals with severe hypertension.

Comparison with other studies

Other studies evaluating task sharing for hypertension management have shown modest levels of success. For example, one randomised controlled study conducted in Ghana using task sharing (but with supplying free medications) showed greater reductions in SBP in patients randomised to the arm that included trained nurses, as compared to the one that just provided free medications and health insurance [10].

The poor follow-up reported in our study is not unexpected. Many studies have shown poor levels of follow up or adherence to clinic appointments. In one study conducted in three primary care clinics in Kibera, Kenya between 2010 and 2012, 1465 hypertensive or diabetic patients were identified. Of these 31% of patients were lost to follow up. Of these 55% of non-diabetic patients had their BP under control by 24 months, but only 28% of diabetic patients [11].

In another study conducted in Kibera, Kenya between 2015 and 2016, 3861 hypertensive patients were identified in health centres or clinics. of those 3069 patients did not complete six months of follow up (79%). Of those patients who remained in the programme over 6 months, they found 63% adherence to appointments [12].

In a study conducted in the slums of Nairobi only 3.4% of participants showed completed compliance with the programme. 30% only showed up for one appointment, and 5% only had two visits. Similar to our study they found that patients who remained in the programme showed significant reductions in SBP and DBP [13].

In a study done in two sites (one rural and one urban) in Malawi, of 4075 patients referred for clinical care, only 61% attended their referral appointments. Of those 47% of hypertensive patients were still in contact after 24 months. Similar to our findings, they found uptake in care to be higher in older patients, being on anti-hypertensives prior to enrolment, and not being in employment. Unlike our study, they found that females were more likely to be retained in care .[14]

Similarly, a study of hypertensive and diabetic patients in rural Cameroon found that only 18.1% of participants were still in care after one year. However similar to our study they found significant decreases in SBP and DBP in hypertensive patients with at least two documented visits.

Strengths and Limitations

A major strength of this study is unlike most other hypertension programmes ComHIP uses existing GHS protocols and medications and does not require outside funds or intervention for medications. This means that there is a much greater chance of long term sustainability of the programme as it does not rely on outside sources for medications.

Limitations of the study include that data were only available for encounters with service providers within the ComHIP network. Any appointments with doctors, pharmacists (licensed or un-licensed) that were not part of ComHIP would not have been registered, so it is possible that patients were obtaining anti-hypertensives from non-licensed sellers, which would not be captured in the ComHIP database. Another limitation of ComHIP was that the cohort did not have a control.

Due to the extremely poor follow-up, it is not possible to generalise our findings regarding the impact on blood pressure control to other studies, other than to emphasize the importance of effective strategies to promote follow-up. Finally, it is important to remember that nearly 70% of the initial cohort was aware of their hypertension status and about half were taking medications, which is a much higher proportion than in the general population. While this was done in ComHIP to ensure access to hypertension management to community members who otherwise would not have been able to access services, it is an important consideration when considering generalisability to the overall population.

Interpretation

In the 25% of people who had a 12-month appointment, there was strong evidence of an increase of the patients receiving medications, the average number of medications received per patient, and the level of hypertension control, we also found a reduction in both BP and hypertension status. However, like most other studies in the region, the high loss to follow up highlights that innovative hypertension programmes such as ComHIP need to develop better ways to retain patients within the programme.

Community based hypertension programmes in resource poor setting often are complex to carry out, and are prone to poor follow-up. There are many possible reasons that follow up in our study was low.

The factor most associated with retention in the programme was enrolment date. This is significant as due to operational issues, there was gap of CommCare utilization for three months. Anecdotally FHI 360 ComHIP staff learned that this gap in CommCare service had caused both service providers and staff to believe that the intervention had stopped, which may have resulted in a low rate of completion of follow-up appointments. Considering difficulties associated with community based studies in low resource settings, it is imperative to ensure continuity of service. Other factors that could cause this association may be health care professional fatigue; engaging patients to present for appointments may require considerable effort, such as multiple phone calls and personal interaction, for which the CVD nurses did not receive additional monetary compensation. It is possible that over time, the enthusiasm of the CVD nurses for the intervention may have waned. Also, as in any low – resource settings, there is a great deal of workforce turnover, FHI 360 recognised this early in the implementation and trained extra staff to bridge the gaps, however it is still possible that new health care providers who replaced them may not have had the same level of training. A complementary component of the evaluation which includes qualitative research with different ComHIP stakeholders is underway to analyse in depth the possible reasons that may have caused people to not adhere to the programme. (see Adler et al Barriers and facilitators to the implementation of a community-based hypertension improvement project in Ghana: A qualitative study and Laar et al Health system challenges to hypertension and related non-communicable diseases prevention and treatment: perspectives from Ghanaian stakeholders)

Lastly, our study found that older individuals were more likely to continue in care, this was found in at least one other study[14] but was not reported on in most studies. This could be because older patients may have more time to attend clinics. Patients with their hypertension under control were about twice as likely to stay in the programme. This is not surprising as they had already exhibited better health seeking behaviours.

Recommendations:

For patients enrolled and who continued in the programme we found an important impact on the management of hypertension and in blood pressure control. However, the high loss to follow-up of patients recruited limits the potential public health impact of these types of programmes. In order to minimize the impact of externalities (such as the CommCare service gap in ComHIP) programmes should have standard procedures and back-up systems to maximize the possibility that patients stay in the programme, particularly younger and less educated individuals. Also, appropriate incentives should be put in place to keep programme staff fully engaged and avoid programme fatigue. Future studies should further identify causes of loss to follow-up and find effective ways to adapt programmes accordingly (e.g. access to treatment within the community, targeted behaviour change messaging) to ensure that most of patients recruited stay long term in the programme. Future research may also want to focus on more difficult to reach patients who have lower levels of awareness and treatment on enrolment.

Acknowledgements
Funding for ComHIP was generously provided by the Novartis Foundation, Basel, Switzerland. We are grateful to all of cohort clients. We are also grateful to the leadership and political support of the Ghana Health Service (both from the national and district levels) for their support.

Competing interests
Co-authors PL, AKL, PP, AJA, and DP-M worked on the ComHIP Programme for which their institutions (LSHTM and UGSPH) have received grants from the Novartis Foundation. Co-authors RD, RD, and DM are staff of the FHI360, which provided technical direction to ComHIP implementation.

Authors' contributions
PL conceived of the project, PL and RD designed the interventions. PL, PP, AKL and AJA designed the research component of the project. DM, and RMMD supervised the implementation of the programme. RMMD is the programme data manager. AJA and DP-M performed the statistical analyses. AJA drafted the manuscript, with inputs from all authors. All authors read and approved the final version of the manuscript.

Consent to publish
Participants' consent was obtained for the purposes of publishing the results from the study. All the authors consented to the study results to be published in the form presented in the final version of this manuscript.

Data sharing
Summary statistics related to the dataset used in the project are available by request

Funding
Funds for the project was made available by Novartis Foundation, Basel, Switzerland. They did not have any input or control over this manuscript.

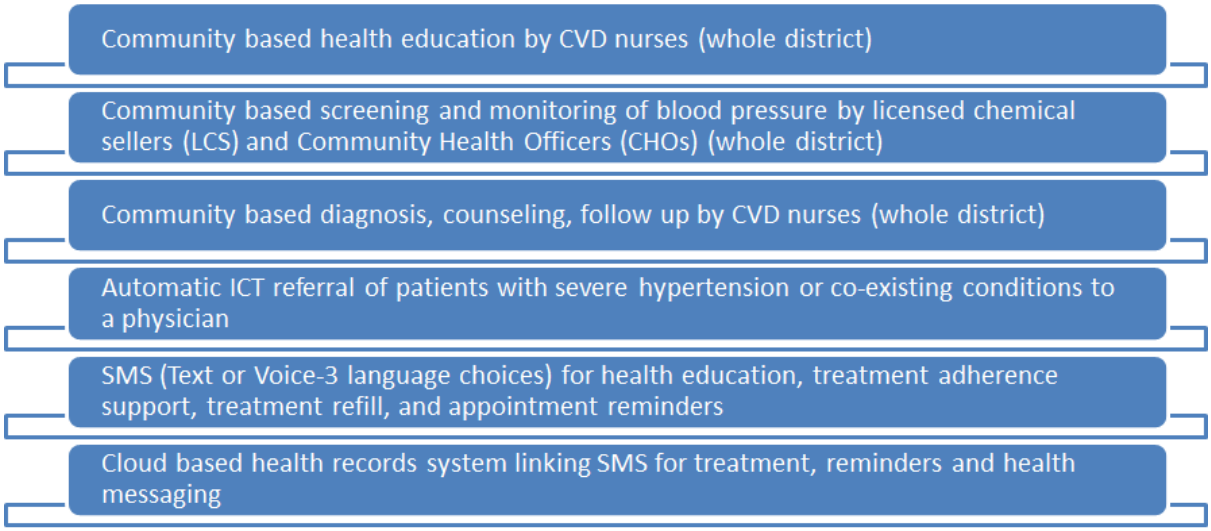
Figures

See attached supplementary file

REFERENCES

1. WHO, *World Health Organization-International Society of Hypertension Guidelines for the Management of Hypertension. Guidelines Subcommittee.* Am J Hypertens, 1999. **17**(2): p. 151–83.
2. Collaboration, B.P.L.T.T., *Effects of blood pressure lowering on cardiovascular risk according to baseline body-mass index: a meta-analysis of randomised trials.* The Lancet, 2015. **385**(9971): p. 867-874.
3. Collins, R., et al., *Blood pressure and coronary heart disease.* Lancet, 1990. **336**(8711): p. 370-1.
4. Law, M.R., J.K. Morris, and N.J. Wald, *Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies.* Bmj, 2009. **338**: p. b1665.

5. Olsen, M.H., et al., *A call to action and a lifecourse strategy to address the global burden of raised blood pressure on current and future generations: the Lancet Commission on hypertension.* Lancet, 2016. **388**(10060): p. 2665-2712.
6. Addo, J., L. Smeeth, and D.A. Leon, *Hypertension in sub-saharan Africa: a systematic review.* Hypertension, 2007. **50**(6): p. 1012-8.
7. Chow, C.K., et al., *Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries.* Jama, 2013. **310**(9): p. 959-68.
8. Lamptey, P., et al., *Evaluation of a community-based hypertension improvement program (ComHIP) in Ghana: data from a baseline survey.* BMC Public Health, 2017. **17**(1): p. 368.
9. GSS, *Population by Region, District, Locality of Residence, Age Groups and Sex, 2010. Accra, Ghana: Ghana Statistical Service.* http://www.statsghana.gov.gh/docfiles/population_by_region_district_locality_of_residence_age_groups_and_sex,_2010.pdf. *Accessed November 22, 2016* 2012.
10. Ogedegbe, G., 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**(5): p. e1002561.
11. Sobry, A., et al., *Caseload, management and treatment outcomes of patients with hypertension and/or diabetes mellitus in a primary health care programme in an informal setting.* Trop Med Int Health, 2014. **19**(1): p. 47-57.
12. Kuria, N., et al., *Compliance to follow up and adherence to medication in hypertensive patients in an urban informal settlement in Kenya: comparison of three models of care.* Trop Med Int Health, 2018.
13. Werner, M.E., et al., *Results of a hypertension and diabetes treatment program in the slums of Nairobi: a retrospective cohort study.* BMC Health Services Research, 2015. **15**: p. 512.
14. Musicha, C., et al., *Accessing clinical services and retention in care following screening for hypertension and diabetes among Malawian adults: an urban/rural comparison.* J Hypertens, 2016. **34**(11): p. 2172-9.



Supplementary figure 1) components of the ComHIP Programme

Visit Number	When?	Activity
1	After patient has been screened and referred by LCS, CHO	CVD Nurse to recheck BP
2	Two weeks after visit 1	1. CVD Nurse to recheck BP and confirm diagnosis 2. Enroll patient, perform risk assessment, perform anthropometric measurements 3. Refer to *Referral SOP for CVD nurse* for all patients that should be referred to Physician. 4. Initiate treatment 5. Order laboratory investigation as needed 6. Perform Hypertension counseling
3	6 weeks after visit 2	1. Re-check BP 2. Assess treatment, perform counseling
4	6 weeks after visit 3	1. Review treatment plan until goal is reached 2. Perform anthropometric measurements every 3 months after enrollment
5 & subsequent visits	• Every 3 months for patients with Mild Hypertension (treated by CVD nurse) • Every 2 months for patient with Moderate Hypertension (treated by CVD nurse) • Monthly for Patients with High (treated by Physicians only)	1. Re-check BP, review treatment, assess for risk factors, perform Hypertension counseling 2. Conduct follow up assessment every 6 months after enrollment

Supplementary Figure 2. guidelines for patient visits

Phase	Activity	Community Health Officer	Licensed Chemical Seller	CVD Nurse	Physician
Phase 1: Screening	Community BP screening	Yes	Yes	No	No
	Screening referral	Yes	Yes	No	No
Phase 2: Diagnostic Evaluation	Confirmation of BP (HTN) diagnosis	No	No	Yes	Yes
	Staging of degree of HTN	No	No	Yes	Yes
	Assessment of other CVD risk factors	No	No	Yes	Yes
	Assessment of prevailing CVD symptoms	No	No	Yes	Yes
	Overall risk assessment/ Stratification	No	No	Yes	Yes
	Assessment of family history of CVD	No	No	Yes	Yes
	Laboratory investigation	No	No	Yes	Yes
	Assessment of target organ complication	No	No	Yes	Yes
	Assessment of Lifestyle Issues	No	No	Yes	Yes
	Diagnostic referral	No	No	Yes	No
	Baseline Anthropometry	No	No	Yes	Yes
Phase 3: Management, Monitoring & Follow Up	Recommendation for drug treatment	No	No	Yes	Yes
	Medication Dispensing	No	Yes	No	No
	Recommendation for Non-drug treatment	Yes	Yes	Yes	Yes
	Evaluation of drug side effects	No	Yes	Yes	Yes
	Monitoring of BP response to treatment	No	Yes	Yes	Yes
	Adherence Counselling	No	Yes	Yes	Yes
	Anthropometric monitoring	No	No	Yes	Yes
	Regular follow up and interaction	No	No	Yes	No
	Management referral	No	No	Yes	Yes*

Supplementary Table 1) Summary of roles of various service delivery personnel
*In rare instances, certain patients may be referred by the Physician to a hypertension specialist

I. Diuretic: Bendroflumethiazide. –initial dose, 2.5mg daily. Maximum dose of 5mg daily.

II. Beta-blocker: Atenolol-initial dose of 50mg daily. Maximum dose of 100mg daily provided the heart rate is greater than 60/min on the lower dose.

III. Calcium channel blocker: Nifedipine retarde or XL -initial dose 30mg daily. Maximum dose of 60 to 90 mg daily.

Supplementary Table 2) Recommended medications and dosages

Community-based Hypertension Improvement Project (COMHIP)

Clinical Guidelines

09.2015

SUMMARY

- This clinical guideline on the management of Hypertension is intended to promote evidence-based management of hypertension in the community and thereby improve patient's clinical outcomes.

- The guideline is intended to assist Licensed Chemical Sellers (LCS), Community Health Officers (CHOs), Cardiovascular Disease (CVD) Nurses and Physicians in the screening and diagnosis of HTN, determination of appropriate treatment, and delivery of individualized pharmacological and non-drug interventions.

- This guideline is general for the ComHIP project and individualized guidelines have been developed for the various service delivery personnel matching their responsibilities.

Table of Contents

1.0 PROJECT DESCRIPTION

- The community-based Hypertension Improvement Project (ComHIP), aims to improve hypertension management and control in Ghana. The project will test a community-based model that engages the private sector and utilizes information and communication technologies (ICTs) to enhance the capacity of the Ghana Health Service and individuals to control hypertension. There are four (4) categories of personnel (Figure 1) involved in service delivery in ComHIP. These are;

    - Community Health Officers
    - Licensed Chemical Sellers
    - Cardiovascular disease nurses
    - Physicians

- Community Health Officers (CHOs) will screen community members; Licensed Chemical Sellers (LCS) will screen clients and contribute to management and follow up of hypersensitive clients; cardiovascular nurses (CVD nurses) will be responsible for confirming hypertension diagnosis, grading and management of clients with mild and forms of hypertension; Physicians will be responsible mainly for managing severe hypertensive clients.

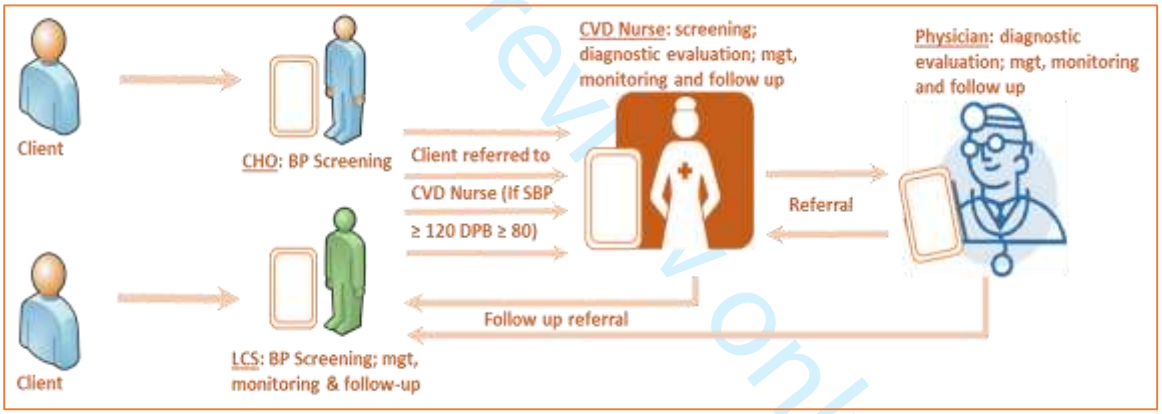


Figure 1: ComHIP Service delivery flow

- ComHIP involves the Ghana Health Service, FHI 360, London School of Hygiene and Tropical Medicine, University of Ghana School of Public Health, VOTO Mobile and with funding support from the Novartis Foundation. The project is for a period of 36 months.

2.0 SUMMARY OF PERSONNEL ROLE

Table 1 summarizes the various functions of licensed chemical sellers (LCS), community health officers (CHOs), cardiovascular disease nurses and Physicians working in ComHIP.

Table 1: Summary of roles of various service delivery personnel

Phase	Activity	Community Health Officer	Licensed Chemical Seller	CVD Nurse	Physician
Phase 1: Screening	Community BP screening	Yes	Yes	No	No
	Screening referral	Yes	Yes	No	No
Phase 2: Diagnostic Evaluation	Confirmation of BP (HTN) diagnosis	No	No	Yes	Yes
	Staging of degree of HTN	No	No	Yes	Yes
	Assessment of other CVD risk factors	No	No	Yes	Yes
	Assessment of prevailing CVD symptoms	No	No	Yes	Yes
	Overall risk assessment/ Stratification	No	No	Yes	Yes
	Assessment of family history of CVD	No	No	Yes	Yes
	Laboratory investigation	No	No	Yes	Yes
	Assessment of target organ complication	No	No	Yes	Yes
	Assessment of Lifestyle Issues	No	No	Yes	Yes
	Diagnostic referral	No	No	Yes	No
	Baseline Anthropometry	No	No	Yes	Yes
Phase 3: Management, Monitoring & Follow Up	Recommendation for drug treatment	No	No	Yes	Yes
	Medication Dispensing	No	Yes	No	No
	Recommendation for Non-drug treatment	Yes	Yes	Yes	Yes
	Evaluation of drug side effects	No	Yes	Yes	Yes
	Monitoring of BP response to treatment	No	Yes	Yes	Yes
	Adherence Counselling	No	Yes	Yes	Yes
	Anthropometric monitoring	No	No	Yes	Yes
	Regular follow up and interaction	No	No	Yes	No
	Management referral	No	No	Yes	Yes*

*In rare instances, certain patients may be referred by the Physician to a hypertension specialist

3.0 SCREENING

3.1 Hypertension Definition and Classification

Hypertension is used to refer to the level of blood pressure (BP) above which treatment does more good than harm. Numerically, hypertension is defined as a systolic blood pressure (SBP) ≥140 mmHg or a diastolic blood pressure (DBP) of ≥90 mmHg. The following BP classification has been adopted;

Table 2: Classification of blood pressure for adults aged ≥18years

BP Classification	Systolic BP (mmHg)		Diastolic BP (mmHg)
Normal	<120	and	<80
Pre-Hypertension*	120-139	or	80–89
Grade 1 Hypertension (Mild)	140–159	or	90-99
Grade 2 Hypertension (Moderate)	160–179	or	100–109
Grade 3 Hypertension (Severe)	≥180	or	≥110

*Pre-hypertension: This refers to patients with very real risk of developing chronic high blood pressure

3.2 BP Screening Protocol

A. Who should conduct screening? LCS, Community Health Officer (CHO)

B. Who is Eligible to be screened? Any adult in the community 18 years and older excluding pregnant women.

C. Where can Screening be done? LCS will conduct screening at their shops. CHOs will conduct screening at CHPS compounds and during outreach/home visits.

D. How should BP be measured? All personnel involved in ComHIP should adopt simple techniques that minimize BP measurement errors: The following are recommended;

i. Ensure a quiet environment
ii. Patient must be rested for at least 5minutes, quiet and comfortable.
iii. Patient must be seated with arm at heart level and feet flat on the floor
iv. Ensure that sleeves are rolled up or any tight clothing removed.
v. Ensure that the individual has not exercised, smoked or consumed foods, alcohol or drinks containing caffeine (such as tea or coffee) at least 30 minutes before measurements
vi. Ensure that client is not acutely ill or injured
vii. Use appropriate size cuff (E.g. too small a cuff can raise BP)
viii. Measure BP in both arms at first; then subsequently only measure in the arm which gave the higher reading.
ix. Each time BP is to be measured, 3 readings must be taken at least 3minutes apart.
x. Refer to BP measurement guide whenever unsure.

E. What to do with BP reading?

I. All clients with BP ≥140/90mmHg must be referred to CVD nurse. Clients with BP in the Pre-hypertension range must be counselled on lifestyle and encourage to check BP regularly.
II. For clients with BP≥180/110 stress the need for urgent/immediate visit to a CVD nurse and arrange this visit with the CVD nurse.

⊠ Remember to explain to client that Screening is not diagnosis. Further investigation would be needed even if you suspect that the high BP may be hypertension.

4.0 DIAGNOSIS AND EVALUATION

4.1 Objectives of diagnostic evaluation

There are four key objectives in the assessment of a person with suspected hypertension are;

1) To confirm whether or not blood pressure is elevated
2) To document the presence or absence of blood pressure related target organ damage (e.g. left ventricular hypertrophy, hypertensive retinopathy, increased albumin: creatinine ratio);
3) To evaluate the person's cardiovascular risk either due to established cardiovascular disease or high cardiovascular disease risk states (e.g. diabetes or CKD), or by calculation of their 10 year CVD risk estimate
4) To consider whether there may be secondary causes for the hypertension.

4.2 Confirmation of hypertension diagnosis

A. Who should confirm HTN diagnosis? For most cases CVD nurse would confirm hypertension status and grade severity. In few instances, Physicians would do this for referred clients.

B. How should BP (HTN) be confirmed? The Following steps are recommended Use two measurements obtained two weeks apart.

i. At each visit, take 3 BP readings and record the mean
ii. Systolic equal or greater than 140 and or diastolic equal or greater than 90 (use mean of the readings obtained at the three separate visits)
iii. For clients with initial BP in grade 3, CVD nurse must provide immediate starting dose and refer to physician

4.3 Grading of the Severity of Hypertension

A. Who should grade severity of hypertension? Usually CVD nurse will be responsible for grading patients, Physicians will confirm severe hypertension grade.

B. How should HTN severity be graded? Use Table 2 (page 6) to grade level of severity.

C. Are there any referrals needed?

I. YES, CVD nurse must refer all patients with severe hypertension to a Physician.

⌦ All confirmed patients 18-30yrs must be referred for further investigation by a physician to rule out possible secondary causes.

4.4 Assessment for other CVD risk factors

A. Who should conduct assessment of CVD risk factors? CVD nurse, Physician

B. **How should CVD risk factors be assessed?** A set of questions are useful in assessing CVD risk factors. Usually a Yes or No response is required from clients by asking the following;

i. Have you had prior history of diabetes or hypertension?
ii. Have you had prior history of elevated serum lipids
iii. Do you currently smoke tobacco on a daily basis, less than daily, or not at all?
iv. In a typical week, how many minutes do you spend engaging in vigorous/high intensity physical work, activities or exercises?
v. Do you drink alcohol?
vi. Have you had prior history of high cholesterol

4.5 Assessment for Target Organ Damage or CVD Event

A. Who should conduct assessment for TOD/CVD events? CVD nurse, Physician

B. How should TOD/CVD event assessment be done? A yes or No responses are usually needed from patients upon asking the following questions;

i. Have you had prior history of heart failure
ii. Have you had prior history of heart attack
iii. Have you had prior history of a stroke or Transient Ischemic Attack (Mini stroke)
iv. Have you had prior history of kidney failure or disease

4.6 Assessment of Family History

A. Who should conduct assessment of family history? CVD nurse, Physician

B. How should family history assessment be done? Enquire from patient about history of any CVD event (stroke, heart attack) in parents and siblings; especially at age of less than 50.

4.7 Assessment of ongoing CVD symptoms

A. Who should conduct assessment of prevailing CVD symptoms? CVD nurse, Physician

B. How should ongoing CVD symptoms be assessed? Enquire from patient to obtain a Yes or No answer using set of questions below;

i. Ask about exertional dyspnea or at rest
ii. Ask about sleep disturbance by shortness of breath
iii. Ask about sleeping with more pillows of preference to sleep in a chair
iv. Ask about cough or wheezing during sleep.
v. Ask about excessive tiredness.
vi. Ask about central severe chest pain that disables the patient.
vii. Ask about feeling weak or wanting to faint
viii. Ask about palpitations
ix. Ask about loss of consciousness, vision, or speech.
x. Ask about weakness or numbness of one side of the body.
xi. Ask about swelling of feet and legs.

4.8 Anthropometric assessment

A. Who should conduct anthropometric measurements? CVD nurse, Physician

B. What anthropometric measurements should be assessed? Weight, Height, Waist Girth. Calculate BMI

C. When should measurements be taken? Obtain accurate measurements during enrollment, thereafter every three months.

D. How should anthropometric measurements be conducted? Follow recommended techniques below for each assessment;

4.81 Weight

This should be measured using a weighing scale. Follow the following steps;

I. Before each measurement, make sure the scale is zero
II. Ask the patient to remove heavy outer clothing (e.g. coats, jackets, shoes etc.)
III. Ask the patient to stand motionless in the middle of the scale platform with the feet slightly apart and the body weight distributed equally on both feet.
IV. Record body mass to nearest 0.1 Kg
V. Ask patient to step off scale

VI. Repeat steps
VII. If the 2 measurements differ by more than 0.4 kg then repeat steps one more
VIII. If two measurement record the average value. If three measurements record the median value.
IX. Refer to Weight measurement guide

4.82 Height

This should be measured using a Stadiometer. Follow the following steps;

- Ask the subject to stand on the centre of the base with their back to the stadiometer
- Ask them to put their feet together and move back until their heels touch the bottom of the stadiometer upright.
- Their buttocks and upper part of their back should also be touching the stadiometer upright. Their head does not have to touch the stadiometer.
- The respondent's head should be in the Frankfort plane.
- This is achieved when the lower edge of the eye socket (the Orbitale) is horizontal with the Tragion [see appendix 5.5].
- The vertex will be the highest point on their head. If their head is not aligned properly, (and for most respondents it probably won't be), ask them to raise or lower their chin until it is in the Frankfort Plane.
- When you are happy that the respondent is in the correct position, ask them to take a deep breath and hold it.
- Lower the headboard until it is in contact with the head. Compress the hair if needed. Make sure you don't bend the headboard from the horizontal, nor move the respondent's head.
- Hold the headboard firmly at its final position and take the reading to the nearest 0.1 cm.
- When you have completed the reading, ask the respondent to step away from the stadiometer.
- Record measurements immediately.
- Refer to height measurement guide for more details

4.83 Waist Circumference

This should be measured using a tape measure. Follow the following steps;

- Ask the patient to place himself in the following manner: Clear the abdominal region, Feet shoulder-width apart, Arms crossed over the chest
- It is suggested to kneel down to the right of the patient in order to measure waist girth; palpate the patient's hips to locate the top of the iliac crest and Draw a horizontal line halfway between the patient's back and abdomen**.**
- Place the measuring tape horizontally around the patient's abdomen. To work comfortably, it is suggested to wrap the tape around the patient's legs and then move it up.
- Align the bottom edge of the tape with your marked point. Gently tighten the tape around the patient's abdomen without depressing the skin.
- It is suggested to request the patient to relax and breathe normally (abdominal muscles should not be contracted). Ask the patient to take 2 or 3 normal breaths. Measure from the zero line of the tape (to the nearest millimetre) at the end of a normal expiration

4.9 Assessment for signs of CVD

A. Who should conduct assessment for signs of CVD? CVD nurse, Physician

B. How should assessment for signs of CVD be conducted?

i. Note a significant difference (>15mmHg) systolic BP in the arms (Nurse & Physician)
ii. Listen to the neck for bruits (Physician)
iii. Feel for irregularity of the radial pulse; also for rates greater than 100bpm. (Nurse & Physician)
iv. Check for displacement of the apex beat. (Physician)
v. Listen to the heart for normal and abnormal sounds (Physician)
vi. Listen to the back of the chest for Crepitation (Physician)
vii. Look and feel for swelling of the legs and feet (Nurse & Physician)

4.10 Risk stratification

A. Who should conduct overall risk assessment/stratification? CVD nurse, Physician

B. What are the general considerations to grade overall risk? Make consideration of the following in grading overall patient risk.

i. Consider the severity of the hypertension (Refer to table 3 below)
ii. Consider the other CVD risk factors of the patient
iii. Consider any target organ damage*

Table 3: Grading of blood pressure values

BP ranges	Pre-Hypertension		Grade 1	Grade 2	Grade 3
	Normal SPB 120–129 DBP 80–84	High normal SPB 130–139 DPB 85–89	SPB 140–159 DPB 90–99	SPB 160–179 DBP 100–109	SBP ≥180 DBP ≥110

⌦ Risk Factors

The following risk factors are included in the risk stratification.

- Men aged >55 years
- Women aged >65 years
- Smoking
- Dyslipidemia
- Family history of premature cardiovascular disease (men aged <55 years, women aged<65 years)
- Abdominal obesity (abdominal circumference ≥102 cm for men, ≥88 cm for women)

⌦ Comorbidities

The following conditions are included where possible in the overall risk assessment;

- Cerebrovascular disease (TIA, stroke) (Nurse & Physician)
- Heart disease (angina, myocardial infarction, heart failure) (Nurse & Physician)
- Chronic renal disease (Nurse & Physician)
- Peripheral vascular disease (Physician)
- Diabetes (Nurse, Physician)

Table 4: CVD Risk stratification for patients

High Risk	• Grade 3 BP, with or without TOD, risk factors and Comorbidities • Grade 2 BP with TOD and/or +2 risk factors
Moderate risk	• Grade 2 BP without TOD, >2 risk factor or comorbidities • Grade 1 with TOD and/or >2 risk factors, comorbidities
Low risk	• Grade1 BP with no TOD, risk factors or co-morbidities

***TOD** is used to refer to damage occurring in major organs fed by the circulatory system (heart, kidneys, brain, eyes) which can sustain damage due to uncontrolled hypertension. TOD will be assessed by history, physical examination and laboratory investigation. However, TOD will mainly be clinically determined as this will be the usual or expected level of care in the study area. Specific TODs will be assessed as below;

a) Heart Failure criteria for assessment;
- paroxysmal nocturnal dyspnea
- orthopnea
- nocturnal cough or wheezing
- sinus tachycardia
- leg and pedal edema
- Objective tests : ECG evidence of left ventricular hypertrophy (LVH)

b) Kidney damage:
- To be assessed with tests- proteinuria and serum creatinine or prior diagnosis of same. Subjective symptoms: Polyuria, nocturia, haematuria

c) Brain damage:
- To be clinically assessed- symptoms of stroke or prior documentation of a stroke.

d) Eye damage
- Examine the fundi for the presence of hypertensive retinopathy. Subjective signs: impaired vision

4.11 Laboratory Investigations

A. Who can order for laboratory investigation? CVD nurse, Physician

B. What laboratory investigations are recommended?
- Physician should prioritize the following investigations;
  I. Complete blood count
  II. Fasting sugar, HbA1c, and lipids
  III. Urinalysis
  IV. Renal profile.
  V. Electrocardiogram **(**ECG)
- CVD nurse should prioritize the following investigations;
  I. ECG
  II. Fasting blood sugar

C. Laboratory prioritization for different risk profiles
- Low Risk: ECG (Nurse)
- Moderate risk: Glucometer FBS,ECG (Nurse)
- High risk: Full range (Physician)

5.0 MANAGEMENT, MONITORING AND FOLLOW UP

5.1 BP Treatment Goal

A. Who should outline BP treatment goal? CVD nurse, Physician

B. What BP treatment goal should be set for a patient? The goal of treatment is to bring all patients to below 140/90mmHg

5.2 Recommendations for Non-drug Treatment

A. Who should make recommendations for non-drug treatment? CVD nurse and Physicians should make recommendations, LCS should reinforce such recommendations

B. Who are the candidates for non-drug treatment? Non-drug measures should be recommended for all clients diagnosed as pre-hypertensive and hypertensive.

C. What non-drug approaches should be recommended? Prioritize the following;

i. Maintenance of Ideal body Weight
ii. Healthy low salt and Low fat diet
iii. Increased fruit and vegetable consumption
iv. No more than two drinks a day
v. No smoking
vi. Regular aerobic exercise; simple daily brisk walk for thirty minutes
vii. Adequate management of stress and anxiety levels

5.3 Recommendation for drug treatment

A. Who should make recommendations for drug treatment? CVD nurse, Physician

B. Which clients are candidates for drug therapy? All enrolled clients (BP ≥140/90mmHg) are candidates for drug therapy supplemented with lifestyle modification irrespective of risk level.

C. Should treatment be initiated with monotherapy or multiple drugs? The decision to begin with a single or dual drugs rests principally on the level at which the clients BP is above goal and on patients overall risk profile. Typically;

i. Begin with a SINGLE drug if BP<20/10mmHg above goal and in low risk patients.
ii. Begin with TWO drugs if BP>20/10mmHg above goal and in moderate and high risk patients.

5.4 Types of Antihypertensive drugs

A. What are the main drugs that can be prescribed? Four (4) drugs are recommended to CVD nurses for starting treatment in eligible patients in the ComHIP study. Physicians will have wider options to address complex patients' needs. The recommended drugs are;

I. Diuretic: Bendroflumethiazide. –initial dose, 2.5mg daily. Maximum dose of 5mg daily.
II. Beta-blocker: Atenolol-initial dose of 50mg daily. Maximum dose of 100mg daily provided the heart rate is greater than 60/min on the lower dose.
III. Calcium channel blocker: Nifedipine retarde or XL -initial dose 30mg daily. Maximum dose of 60 to 90 mg daily.
IV. ACE Inhibitor: Lisinopril-initial dose of 20mg daily. Maximum dose of 30mg daily.

5.5 Titration of antihypertensive medications (CVD Nurses): Low and Moderate risk patients

- The following steps should guide CVD nurses in the dose titration of hypertensive medications;

A. Patients with a difference between enrollment and goal BP that is less than 20/10mmHg

- Start with only bendrofluomethiazide. (See Appendix 7.2)
- Add atenolol or nifedipine or Lisinopril if BP is greater than goal of 140/90 after three months of bendrofluomethiazide.
- Wait for three more months and if BP is still greater than 140/90, increase the dosage of the atenolol or nifedipine or Lisinopril.
- Wait for another three months and refer patient to a physician if BP is still greater than 140/90

- Key point: For clients with BP<20/10 above goal, typically they will undergo 9months of therapy after which failure to attain BP goal will call for referral to a physician at hospital. However, referral may be made anytime if any complication or serious adverse effects occur within this 9-month period. Patient monitoring should be done every 6weeks irrespective of whether change in therapy or not.

B. Patients with a difference between enrollment and goal BP that is greater than 20/10

- Start with bendro AND atenolol or nifedipine or Lisinopril
- After three months if BP is greater than 140/90, increase the dosage of the atenolol or nifedipine or Lisinopril.
- If BP remains greater than 140/90 three months later, then refer to physician.

- Key point: For clients with BP≥20/10 above goal, typically they will undergo 6months of therapy after which failure to attain BP goal will call for referral to a physician at hospital. However, referral may be made anytime if any complication or serious adverse effects occur within this 9-month period. Patient monitoring should be done every 6weeks irrespective of whether change in therapy or not.

5.6 Titration of antihypertensive medications (Physicians): High risk patients

- The following steps should guide physicians in the selection and dose titration of hypertensive medications.

A. What drugs are available to physicians? All the classes of antihypertensive below;

a) Diuretic: bendroflumethiazide.-2.5mg daily
b) Calcium Channel Blocker (CCB): Amlodipine 5-10mg or Nifedipine (SR) 20-60mg daily
c) Beta Blocker: Atenolol 50-100mg daily
d) Angiotensin Converting Enzyme (ACE) Inhibitor: Lisinopril 10-30mg daily
e) ARB: Losartan 50-100mg daily

- Additional options like centrally acting agents, alpha blockers, aldosterone antagonist may be available to physicians

B. What are the acceptable and possible combinations? The possible combinations are a+b; a+c; a+d; a+e; b+d; b+c; b+e

- The choice may be influenced by the presence of the patient's other medical conditions
- Titrate dose or add additional drug to lower the BP to goal.

C. Recommendations for compelling indications

There is evidence to support the use or avoidance of certain antihypertensive when other conditions are present. These include the following;

Table 5: Compelling indications for individual drug classes

compelling indications	initial therapy options
Heart Failure	THIAZ, BB, ACEI, ARB, ALDO ANT
Post Myocardial Infarction	BB, ACEI, ALDO ANT
High CVD risk	THIAZ, BB, ACEI, CCB
Diabetes	THIAZ, BB, ACEI, ARB, CCB
Chronic Kidney Disease	ACEI, ARB
Recurrent Stroke Prevention	THIAZ,ACEI

Keys: THIAZ=thiazide diuretic, ACEI=angiotensin converting enzyme inhibitors, ARB=angiotensin receptor blocker, BB=Beta-blocker, CCB=calcium channel blocker, ALDO ANT=aldosterone antagonist

5.7 General Prescribing Guideline

A. Who should prescribe antihypertensive medicines? CVD Nurse, Physician

B. Before prescribing medicines confirm that patient agrees to be on medications

C. How should prescriptions be written? Follow the steps below;

i. written legibly in ink or otherwise so as to be indelible
ii. written by the prescriber (CVD Nurse, Physician) and not left for someone to complete
iii. should be dated
iv. The full name and address of the patient should be stated
v. Dosage form, generic name of medication, strength, dose and dosage schedule
vi. Exact quantity of medication to be supplied
vii. the signature of the prescriber(CVD nurse, Physician) (which should be in ink)

5.8 Side Effect Monitoring

A. Who should monitor side effects in patients? CVD nurse, LCS, Physician

B. What are the possible side effects of various medicines? See below;

i. ACE Inhibitors: swelling of lips, tongue and throat; the patient must be advised to seek immediate medical help. They can cause irritating dry cough.
ii. Beta blockers: worsening or precipitation of asthma; bradycardia; worsening of HF
iii. Calcium channel blockers: edema of the feet
iv. Diuretic: low potassium leading to generalized weakness.

5.9 monitoring of response to treatment

A. Who should monitor clients' response to treatment? CVD nurse, Physician, LCS

B. What should be the monitoring priorities? see key focus below

i. Aim for goal BP reading
ii. Monitor for side effects
iii. Check for adherence to the non-drug measures for BP control
iv. For resistant hypertension consider evaluation for interfering substances
v. Also consider specialty consultation for patients with resistant hypertension.

5.10 General dispensing Guideline (For LCS only)

A. Who should dispense medication? LCS

B. What checks should be done before dispensing medicines? LCS should ensure that;

i. the prescription is legally valid, genuine and has not been altered after issuing
ii. Each medicine on the prescription contain the dosage form, generic name, strength, dose, dosage schedule and quantity of medication to be supplied
iii. The prescription is assessed for validity, safety and clinical appropriateness.

C. How should medicines be labelled? Each dispensed medication should be appropriately packaged and adequately labelled with the following minimum information:

i. Name of the patient and the generic name of the medicine
ii. Strength of the active ingredient and special instructions
iii. Quantity of dispensed product
iv. Complete dose regimen in written and/or graphic form
v. Duration of use
vi. Name and address of the LCS facility and dispenser
vii. Date of dispensing

⊠ Dispenser should always ensure that patient fully understands how the medication should be taken before leaving premises.

5.11 Hypertensive Emergencies

⊠ Severe hypertension, usually BP>180/110 mmHg in adults may be associated with acute neurological, cardiovascular or renal compromise, and could be fatal.

- If an LCS or CHO records BP reading for a client in this range, arrangements must be made immediately to see a CVD nurse must immediately administer oral hydralazine 10mg and refer to a physician. Arrange with the physician for the patient's visit
- Physician to administer hydralazine IV 5-10 mg slowly over 20 minutes. This dose may be repeated after 20-30minutes, until the patient is conscious and can take oral medications.

5.12 Referral SOP for CVD nurse

A. Mild/Moderate risk Patients

- All confirmed hypertensive clients' 18-30years should be referred to a physician for further investigation.
- All clients with suspected secondary causes should be referred to a Physician
- All mild and moderate hypertensive clients with no change in BP levels within the first 90 days (resistant hypertension) of treatment should be referred to a physician.
- Clients who have developed intolerable side effects should be referred
- All clients who develop hypertension-related complication should be referred to a physician
- All clients who show signs of target organ damage while under treatment should be referred to a physician.
- Any client who experiences a cardiovascular event while under treatment should be referred to a physician

B. High risk Patients

- All severe/high risk patients should be referred to a physician
- All clients with history of unstable stroke or cardiovascular event should be referred to a physician

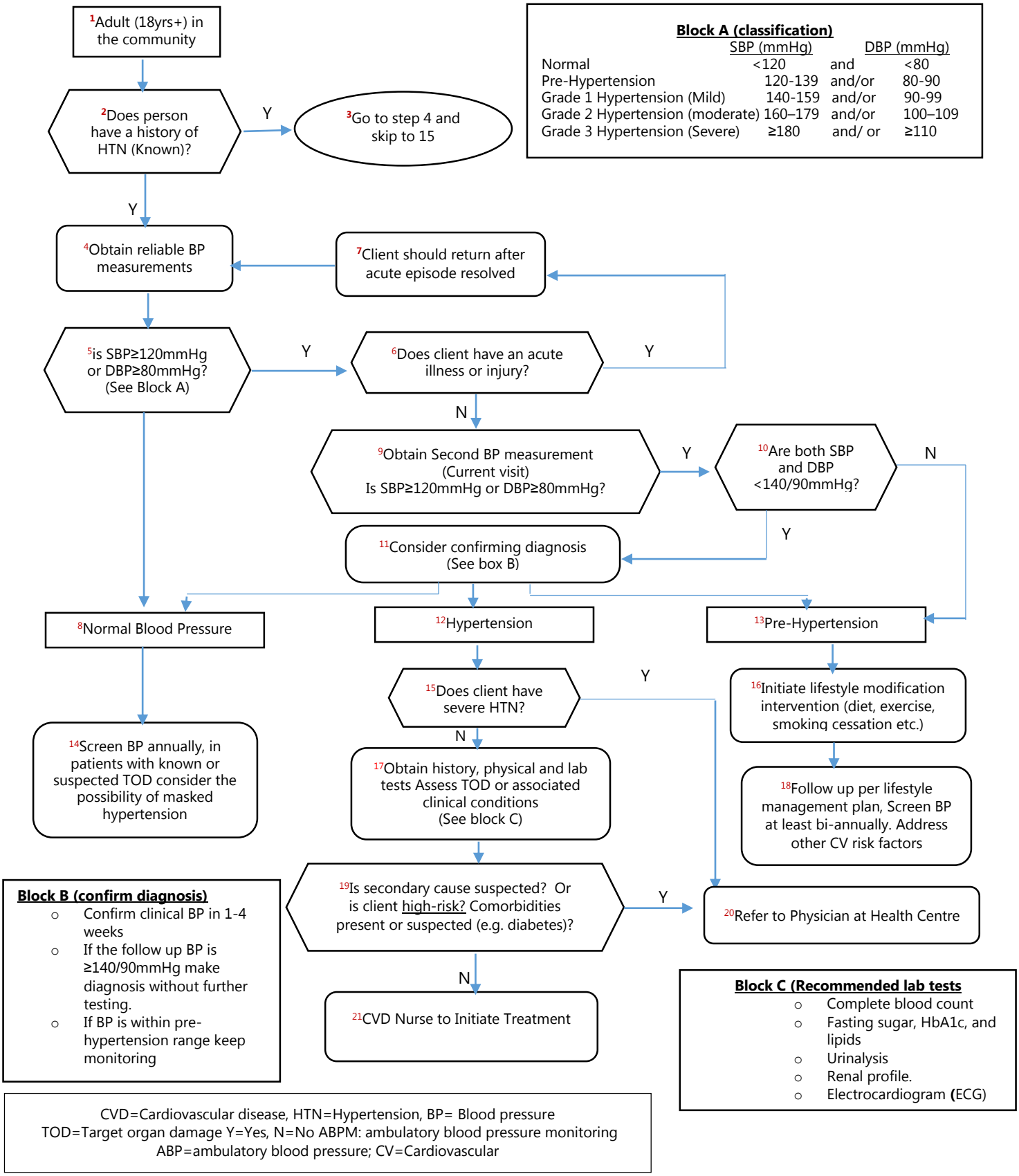
5.13 Proposed activities for patients' visit

The following is aimed at helping CVD nurses determine what needs to be done at a patients visit.

Table 6: Patient Visits and proposed activities

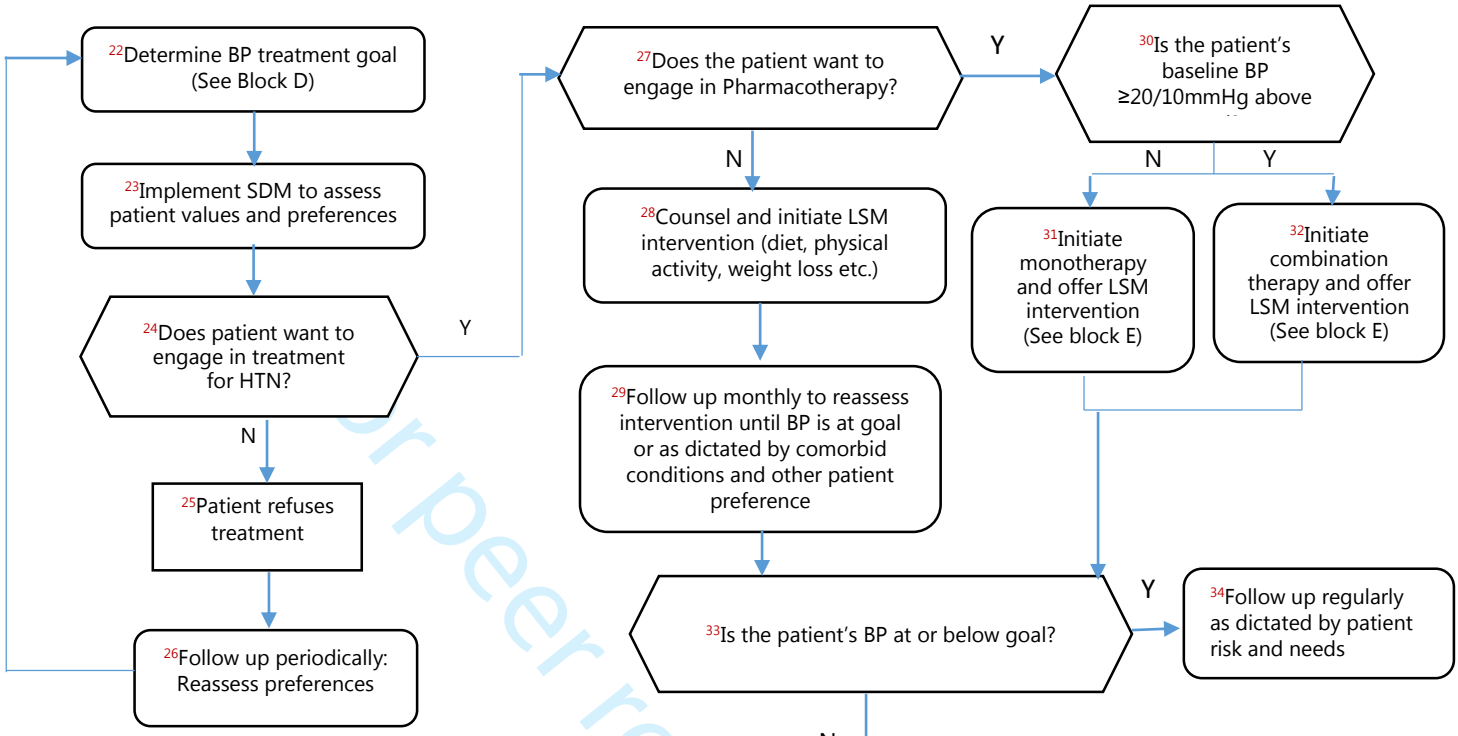
Visit Number	When	Activity
1	After patient has been screened and referred by LCS, CHO	CVD Nurse to recheck BP
2	Two weeks after visit 1	1. CVD Nurse to recheck BP and confirm diagnosis 2. Enroll patient, perform risk assessment, perform anthropometric measurements 3. Refer to Referral SOP for CVD nurse for all patients that should be referred to Physician. 4. Initiate treatment 5. Order laboratory investigation as needed 6. Perform Hypertension counseling
3	6 weeks after visit 2	1. Re-check BP 2. Assess treatment, perform counseling
4	6 weeks after visit 3	1. Review treatment plan until goal is reached 2. Perform anthropometric measurements every 3 months after enrollment
5 & subsequent visits	• Every 3 months for patients with Mild Hypertension (treated by CVD nurse) • Every 2 months for patient with Moderate Hypertension (treated by CVD nurse) • Monthly for Patients with High (treated by Physicians only)	1. Re-check BP, review treatment, assess for risk factors, perform Hypertension counseling 2. Conduct follow up assessment every 6 months after enrollment

6.0 SCREENING AND DIAGNOSIS ALGORITHM



CVD=Cardiovascular disease, HTN=Hypertension, BP= Blood pressure
TOD=Target organ damage Y=Yes, N=No ABPM: ambulatory blood pressure monitoring
ABP=ambulatory blood pressure; CV=Cardiovascular

7.0 MANAGEMENT FLOW ALGORITHM



Block D (Treatment Goals)

- Goal is to bring BP to 140/90mmHg or below
- In Diabetics the aim is 130/80mmHg or below

Block E (Initiate Drug Therapy)

- 1st Line: Thiazide-type diuretics
- 2nd Line: ACEIs, ARBs, CCBs, Long-acting DHP
- 3rd Line: Aldosterone antagonist or Potassium-sparing diuretic or Alpha-blocker or Beta-blocker

Block F (Optimize management)

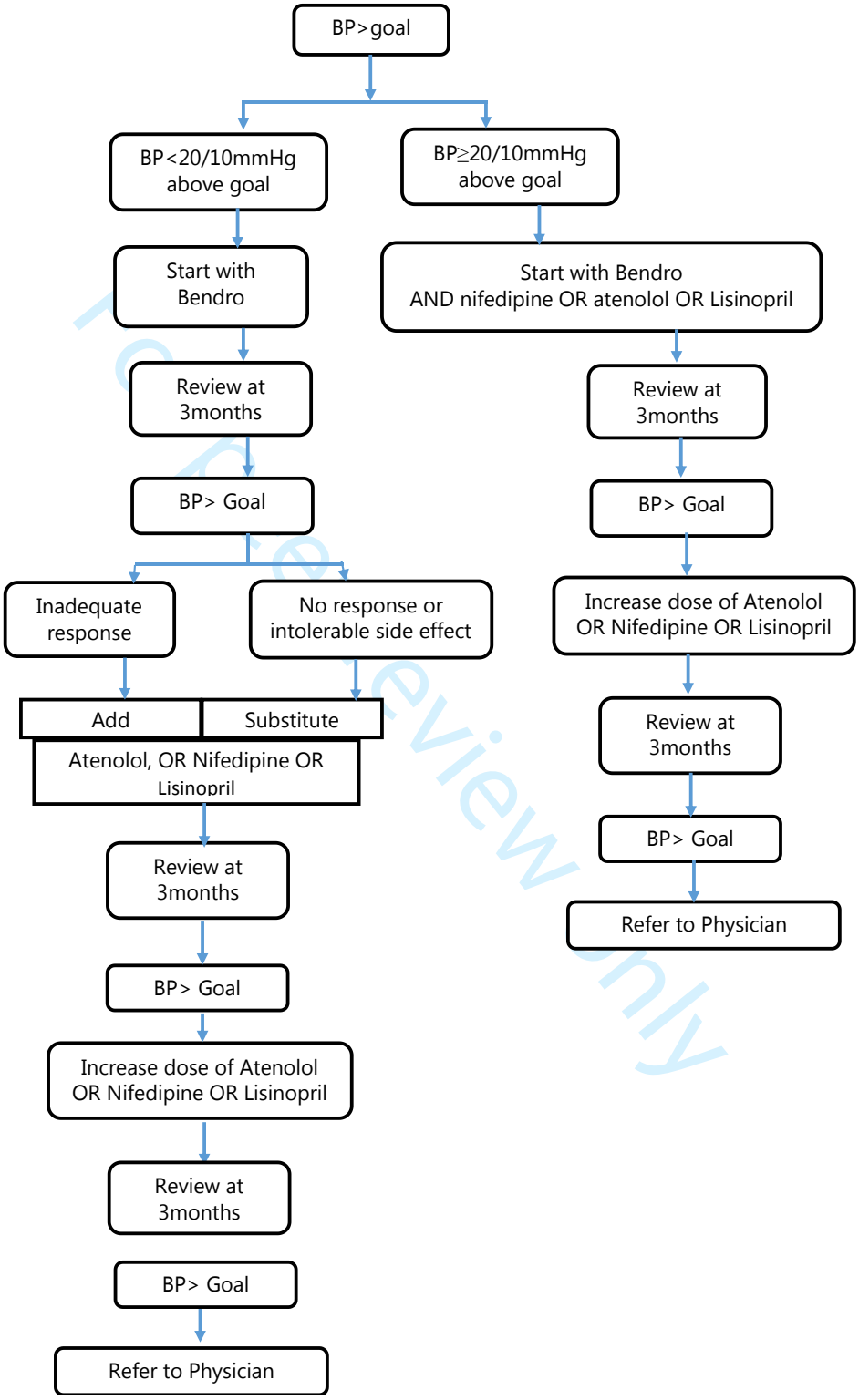
- Optimize treatment
  - Titrate initial drug (s)
  - Add another agent from different class
- Assess adherence
- Reevaluate diagnosis (resistant HTN)
  - Consider evaluation for interfering substances or contributing secondary causes of hypertension
  - Consider specialty consultation for patients with resistant hypertension

7.0 APPENDIX

7.1 Summary of GHS and NHIA approved drugs

Class	Medicine	Recommended in GHS treatment guideline	Available on NHIS Medicines List	Reimbursement NHIA cost (GHC)
Diuretics	Bendroflumethiazide 2.5mg	Yes	Yes	0.06/tab
	Bendroflumethiazide 5mg	No	Yes	0.06/tab
	Spironolactone 25mg	No	Yes	0.40/tab
	Spironolactone 50mg	No	Yes	0.70/tab
Beta-Blockers	Atenolol 25mg	Yes	Yes	0.10/tab
	Atenolol 50mg	Yes	Yes	0.10/tab
	Atenolol 100mg	Yes	Yes	0.13/tab
	Bisoprolol	Yes	No	n.a
	Carvedilol	Yes	No	n.a
ACE inhibitors	Lisinopril 2.5mg	Yes	Yes	0.18/tab
	Lisinopril 5mg	Yes	Yes	0.20/tab
	Lisinopril 10mg	Yes	Yes	0.25/tab
	Lisinopril 20mg	Yes	Yes	0.30/tab
	Ramipril 2.5mg	Yes	Yes	0.22/tab
	Ramipril 5mg	Yes	Yes	0.40/tab
ARBs	Losartan 25mg	Yes	Yes	0.36/tab
	Losartan 50mg	Yes	Yes	0.50/tab
	Losartan 100mg	Yes	Yes	1.0/tab
	Candesartan	Yes	No	n.a
	Valsartan	Yes	No	n.a
Calcium Channel Blockers	Nifedipine 10mg (capsule)	No	Yes	0.35/cap
	Nifedipine 10mg (SR)	Yes	Yes	0.21/tab
	Nifedipine 20mg (SR)	Yes	Yes	0.17/tab
	Nifedipine 30mg XL (GITS)	Yes	Yes	0.47/tab
	Amlodipine 5mg	Yes	Yes	0.20/tab
	Amlodipine 10mg	Yes	Yes	0.30/tab
Alpha Blockers	Prazosin 500mcg	Yes	Yes	0.60/tab
Centrally acting agents	Methyldopa 250mg	Yes	Yes	0.25/tab
Vasodilators	Hydralazine 25mg	Yes	Yes	0.70/tab
Combination therapies	Atenolol + Hydrochlorothiazide (50+25mg)	No	Yes	1.00/tab
	Atenolol + Hydrochlorothiazide (100mg +25mg)	No	Yes	2.10/tab
	Lisinopril + Hydrochlorothiazide (10mg+12.5mg)	No	Yes	1.00/tab
	Lisinopril + Hydrochlorothiazide (20mg+12.5mg)	No	Yes	2.05/tab

7.2 Drug Management Flow diagram for CVD nurses



STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	7
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-8
		(b) Give reasons for non-participation at each stage	7-8
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7-9
		(b) Indicate number of participants with missing data for each variable of interest	7-9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7-9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	10-13
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Can a nurse-led community based model of hypertension care improve hypertension control in Ghana? Results from the ComHIP cohort study.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2018-026799.R2
Article Type:	Research
Date Submitted by the Author:	06-Feb-2019
Complete List of Authors:	Adler, Alma; London School of Hygiene & Tropical Medicine, Department of Non-communicable Disease Epidemiology; Harvard Medical School Laar, Amos; School of Public Health, University of Ghana, Department of Population, Family & Reproductive Health Prieto-Merino, David; London School of Hygiene and Tropical Medicine, Department of Non-communicable Disease Epidemiology Der, Reina; Family Health International Mangortey, Debbie ; Family Health International Dirks, Rebecca; Family Health International Lamptey, Peter; London School of Hygiene & Tropical Medicine, Department of Non-communicable Disease Epidemiology Perel, Pablo; London School of Hygiene and Tropical Medicine, Department of Non-Communicable Disease Epidemiology
Primary Subject Heading:	Global health
Secondary Subject Heading:	Epidemiology, Public health
Keywords:	Hypertension < CARDIOLOGY, cohort, EPIDEMIOLOGY

Can a nurse-led community based model of hypertension care improve hypertension control in Ghana? Results from the ComHIP cohort study.

Alma J Adler[12*], Amos K Laar[3*], David Prieto-Merino[1], Reina M. M. Der[4], Debbie Mangortey[4], Rebecca Dirks[5], Peter Lamptey[1], Pablo Perel[1]

***Co-first authors**

Correspondence:
Dr. Alma J Adler
alma.adler@lshtm.ac.uk

[1]Department of Non-communicable Disease Epidemiology. London School of Hygiene & Tropical Medicine. Keppel St, London. WC1E 7HT

[2]Department of Global Health and Social Medicine, Harvard Medical School. Boston, MA, United States

[3]Department of Population, Family, & Reproductive Health, School of Public Health, University of Ghana, LG 13, Legon, Accra, Ghana.

[4]FHI 360, Accra, Ghana

[5]FHI360, Washington DC, United States.

Alma J Adler alma.adler@lshtm.ac.uk
Amos K Laar alaar@ug.edu.gh
David Prieto -Merino david.prieto@lshtm.ac.uk
Reina M. M. Der RDer@fhi360.org
Debbie Mangortey DMangortey@fhi360.org
Rebecca Dirks rdirks@fhi360.org
Peter Lamptey plamptey@fhi360.org
Pablo Perel pablo.perel@lshtm.ac.uk

Word count: 4435

Abstract:

Objectives: to evaluate the effectiveness of the Community-Based Hypertension Improvement Project (ComHIP) in increasing hypertension control.

Setting: Lower Manya Krobo, Eastern Region, Ghana.

Participants: All adult hypertensive community members, except pregnant women, were eligible for inclusion in the study. We enrolled 1339 participants, 69% of which were female. 552 had a six-month visit, and 338 had a 12-month visit.

Interventions: We report on a package of interventions where community based CVD nurses were trained by Family Health International (FHI360). CVD nurses confirmed diagnoses of known hypertensives and newly screened individuals. Participants were treated according to clinical guidelines established through the project's Technical Steering Committee. Patients received three types of reminder and adherence messages. We used CommCare, a cloud based system, as a case management and referral tool.

Primary outcome: Hypertension control defined as blood pressure under 140/90 mm Hg. Secondary outcomes: Changes in blood pressure and knowledge of risk factors for hypertension.

Results: After one year of intervention 72% (95% CI 67%, 77%) of participants had their hypertension under control. Systolic BP was reduced by -12.2 mmHg (95%CI 14.4, -10.1) and diastolic BP by -7.5 mmHg (95%CI 9.9, 6.1). Due to low retention, we were unable to look at knowledge of risk factors. Factors associated with remaining in the programme for 12-months included education, older age, hypertension under control at enrollment, and enrollment date. The majority of patients who remained in the programme were on treatment, with two-thirds taking at least two medications.

Conclusions: Patients retained in ComHIP had increased BP control. However, high loss to follow-up limits potential public health impact of these types of programmes. To minimize impact of externalities, programmes should include standard procedures and back-up systems to maximize the possibility that patients stay in the programme.

Keywords:

Hypertension, Ghana, Community based cohort study.

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ComHIP is a large cohort study testing a community based model of hypertension care
- Trained community based cardiovascular nurses conducted screening, diagnosis and management of hypertension patients
- Patients were sent three types of SMS, daily reminders to take their medications, appointment reminders, and weekly health education messages
- Protocol stated that blood pressure would be checked with a minimum of three serial readings at regular intervals, but at a minimum of 6-monthly intervals

- a limitation of the study was that it did not include a control group

INTRODUCTION:

Globally, raised systolic blood pressure (SBP) is one of the greatest risk factors for disability [1]. Hypertension is generally considered to be the level of raised blood pressure (BP) where medications show a reduction in clinical events in randomized trials. This is generally accepted as ≥140 SBP mmHg or ≥90 diastolic mmHg (DBP)[2].

Evidence shows that lowering hypertensive individual's blood pressure with anti-hypertensive drugs reduces the risk of further cardiovascular events; with a reduction in stroke by an estimated 35–40% and a myocardial infarction and heart failure reduced by 20–25% reduction [3-5]. Whilst average age-standardised BP is decreasing in most high-income countries, it is increasing in most low and middle income countries (LMICs) [6] with 32% to 50% of adults estimated to be hypertensive in sub-Saharan Africa [7].

The Prospective Urban Rural Epidemiology (PURE) study showed that despite high levels of hypertension worldwide, only 34% of Africans are aware of their hypertension status, only 31.3% receive any treatment and only 6.5% have their blood pressure under control .[8] Our recent study of hypertension prevalence in the Lower Manya Krobo, Ghana, showed that only 2.1% of hypertensives had their blood pressure under control [9].

Because of the great burden of hypertension in Sub-Saharan Africa and the poor rate of hypertension control, innovative methods for hypertension management are needed. Launched in 2015, the Community-Based Hypertension Improvement Project (ComHIP) introduced an innovative model for hypertension control at the community level. ComHIP is a public-private partnership between the Ghana Health Service, FHI 360 and the Novartis Foundation.

The aim of ComHIP is to improve hypertension management and control in the Lower Manya Krobo district in the Eastern Region of Ghana. The programme includes a package of interventions composed of six components (Supplementary Figure 1), aimed at increasing access to hypertension services at the community level. Screening in the community is provided by Cardiovascular Disease (CVD) nurses and Community Health Officers (CHOs), as well as through local private sector drug shops called licensed chemical sellers (LCS). Ongoing hypertension management is provided by CVD nurses or, for those with co-morbidities or severe conditions, at district hospitals. Patients are encouraged to routinely monitor their blood pressure by having their BP measured at a LCS. The various service providers are linked through a cloud-based system which revolve around bringing hypertension care into the community. Physicians, Community based CVD nurses, CHOs, and LCS staff were trained by FHI 360 to provide specific services.

For instance, CVD nurses conduct hypertension screening, and confirmation of hypertension diagnosis, staging of degree of hypertension, assessment of other CVD risk factors, counselling, monitoring and follow up and trained LCS conduct community BP screening and awareness raising. Further information is found in the supplementary material.

The ComHIP Programme is being independently evaluated by the University of Ghana School of Public Health and the London School of Hygiene & Tropical Medicine with a mixed method approach through a series of quantitative and qualitative studies. These studies include repeat cross-sectional surveys within the intervention and comparison districts to track overall awareness and prevalence of hypertension; a cohort of hypertensive persons included in ComHIP to assess hypertension control; a

cost-effectiveness evaluation; a study to assess the level of patient-centeredness within the programme; and a qualitative assessment of ComHIP stakeholders. In this paper we report the results of the cohort study.

Objectives

The objective of this study was to evaluate the effectiveness of ComHIP for controlling hypertension in patients with hypertension enrolled into the ComHIP programme.

METHODS:

Study design

The study was a prospective cohort study which included all patients recruited into the ComHIP Programme.

Setting

The study was conducted in Lower Manya Krobo, a municipality in the Eastern region of Ghana. This is a peri-urban setting approximately two hours from the national capital, Accra with a population of approximately 89,246, of whom 84% live in urban areas.[10] Recruitment began October 2015 and ended in December 2016.

Training

FHI360 and the MoH conducted training. Training duration ranged from three days for LCS, and physicians to 6 days for CVD nurses. Aside from the general training package (BP screening including the recommended standard operating procedures for BP checking, Lifestyle modification counselling, interviewing/counselling techniques, treatment adherence counselling) offered to all personnel, CVD nurses and physicians received additional training on hypertension diagnosis, assessing the risk of patients. Assessing for TODs, drugs for the management of hypertension and their side effects and contraindications.

Participants were issued certificate of participation signed by the cardiologist specialist who conducted the training and the director general of the GHS. Also, as is done by the GHS the continuous learning log books of the GHS personnel were endorsed by the project to document the training received.

Participants

Patients were enrolled into the programme if 1) they were known hypertensives or 2) had an elevated blood pressure reading at any ComHIP screening. Any individual living in Lower Manya Krobo 18 years or older was eligible, except pregnant women. Patients had to have access to a mobile phone to be enrolled in the programme. However, in order to negate loss of patients, patients without phones were not necessarily excluded based on this, rather, they were encouraged to provide phone numbers of a willing third party who lived nearby.

Intervention

Community members were screened by CHOs, LCS, or CVD nurses, using Omron M6 BP monitors that came with a cuff size of 42 cm which is about the 2nd largest cuff size in the market for those machines. Though the project requested for nurses to report cases of patient with bigger upper arms that required bigger cuff sizes, throughout the implementation, no such reports was received. The average of three serial readings was used to confirm hypertension diagnosis. Patients who were at risk of hypertension (SBP ≥120, but <140) were given health education. All patients with SBP≥140 or DBP ≥90 were referred to a CVD nurse for diagnosis. Patients with SBP ≥180 or DBP ≥110 were enrolled and referred to the physician for urgent care. Patients that were considered to have severe hypertension, (SBP ≥180 or DBP ≥110 or SBP between 160 – 179 or DBP 100 – 109 with one or more risk factors, or any evidence of organ damage see Appendix A) were referred for management by a physician at one of the district hospitals, until their blood pressure was stable, and then they were returned to CVD nurses for care. All other patients were managed by CVD nurses.

Patients with hypertension were enrolled and followed for at least one year. All patient interactions (with LCS, CHOs, CVD nurses, community and hospital pharmacist and doctors) were recorded and uploaded through the CommCare platform. Patients were requested to present for appointments at the following intervals; monthly BP monitoring appointments, monthly, bi-monthly or quarterly review visits (depending on risk factors and personal factors); and six-monthly follow up assessments. Participants were recruited from October 2015 until December 2016, and followed through December 2017. Guidelines for patient visits can be found in the supplementary materials (Supplementary Table 1 and Supplementary Figure 2, Appendix A).

All enrolled participants were treated based on the same clinical guidelines established through the project's Technical Steering Committee, which included senior members of the GHS. The treatment goal was to improve blood pressure of all patients to below 140/90 mmHg. Participants were initiated onto drug therapy and supplemented with non-drug therapy (lifestyle modification including low salt diets, increased fruit and vegetable diet, reduction in alcohol consumption, smoking cessation and regular aerobic exercise) irrespective of their risk level. The decision to initiate a monotherapy or multiple drug therapy depended largely on the level at which the participants BP was above goal and the overall risk level of patients. Recommended drugs and dosages are found in supplementary Table 2. Patient's response to antihypertensive were reviewed every three months if possible and modified based on recommended guidelines if required. In Ghana, there is a system of National Health Insurance, and every Ghanaian is required to enrol in. The Scheme provides select medications at no cost for anyone who has a valid National Health Insurance card. Although the NHIS does not attempt to treat all diseases suffered by insured members, over 95% of disease conditions that afflict us are covered by the NHIS. Services can be accessed at accredited health facilities.

CommCare is a vital component of ComHIP. It serves as a case management system, referral tool, and job aid for providers. The CommCare database is linked with a SMS platform to automatically send daily adherence reminders, weekly healthy living tips, and consultation and prescription refill reminders to enrolled patients. These messages are sent via text or voice SMS with four language choices. The programme is described in more detail elsewhere [9]. Briefly, through CommCare patients diagnosed with severe hypertension or co-existing conditions are automatically referred to a physician. All patients enrolled in ComHIP receive SMS daily for medication reminders, weekly for

health education, and upon need for appointment and screening reminders. CommCare also provides a cloud based health records system that links patients' records with the SMS system. The SMS component of the project was implemented by a third party Viamo, to facilitate the link between the two systems a bridge was built to automatically relay relevant information from the projects cloud-based health records to the Viamo messaging platform. To ensure confidentiality, only information relevant to schedule appoints is relayed to the Viamo platform (i.e. patient code, date of visit, type of visit, next review or refill appoint, patient's phone number, preferred, language, time of receipt of message and format of message, referral details and BP). When a visit is missed, the system, automatically relays back to the CVD nurse who enrolled the Patient or is managing the Patient via text message for the nurse to trace the patient. Due to operational problems, there was a break in service in CommCare that began on 12 May 2016 for a period of at least three months.

Variables

Main outcomes:

The main outcomes of interest were hypertension control (<140/90 mmHg), and changes in systolic and diastolic blood pressure. Because of the low follow up rate, we also used appointment around six months, and appointment around 12 months as outcomes of interest.

Other variables:

Other variables included knowledge of risk factors for hypertension, demographic factors including age, gender and marital status; risk factors such as body -mass index (BMI), awareness of hypertension (defined as having knowledge of a previous diagnosis of hypertension), having hypertension under control prior to enrolment, and having previous diagnoses of other heart diseases, and socioeconomic factors. A full list of variables is found in Table 1.

Data collection

Data were collected on blood pressure using standardised protocols. At six and 12 months forms were administered by health care providers to collect information on patient knowledge of risk factors for hypertension and health behaviours.

All data were collected and downloaded from the CommCare platform. Initially data was intended to be analysed from the patient knowledge/behaviour forms used at six-month and 12-month follow up appointments. Due to poor levels of follow up, any appointment between five and seven months after enrolment was used for the six-month appointment analysis, and any appointment between 11 and 13 months after enrolment was used for the 12-month appointment analysis.

Sample size

This cohort study included all the patients recruited in the ComHIP programme and a specific sample size was not calculated. However, in the protocol we assumed that the total district population is about 90,000; about 30,000, of whom are adults, and about 36% [12000] are estimated to be hypertensive. Assuming that about 10% of the adults with hypertension in the district will be included in the ComHIP Programme we would have a cohort of 1,200 patients with hypertension.

We estimated that a cohort study of 1200 patients with hypertension would provide a power greater than 90% (with an alpha error of 0.05) to detect a two-fold increase of control of hypertension (from 4% to 8%).

Patient and Public Involvement

Community members, including community leaders, were first involved through a stakeholder workshop. In this workshop, community members shared their thoughts, knowledge, and concerns about health in general, NCD-related conditions, and access to healthcare. Furthermore, community members were made aware of the hypertension project planned to be initiated in their community. This information was considered in finalizing the design of the service delivery model and the development of prevention, education, and behaviour change messages.

Patients were recruited into the project through free screening offered at 1) local drug shops, names Licensed Chemical Sellers; 2) Community Health Planning Service (CHPS) sites; or 3) Community pharmacies. There were community screening activities and radio programs through which community members were educated on the project and hypertension in general. In addition, ComHIP staff conducted annual stakeholder meetings to provide updates to community members on the project progress.

Statistical methods

We recoded exposures to reduce the number of levels and of missing values: For all the previous diagnosis / awareness: We have coded "missing" or "not known" or "no answer" as 0, so that value 1 always means "Patient knows of a previous diagnosis" while value 0 means anything else (patient does not know or answer is missing). Because there were few previous diagnoses of each specific event (MI, stroke, diabetes…) we created a variable with value 1 if any diagnosis was present and 0 if none was present.

For education, we assumed that those that did not know (48) or did not respond (26) did not have previous formal education (the largest group). We then grouped education in 4 levels: 1) no formal education, 2) primary (completed or not) 3) secondary (completed or not) and 4) higher (university)

For marital status, we made 4 categories: 1) Never married 2) married or cohabiting 3) separated or divorced 4) widowed.

We described the distribution of each variable at baseline, six-months and 12-months follow up, although comparisons cannot be done directly due to the large number of individuals that did not have follow up. To study what variables might affect the patient staying for 12-months in the programme we ran a logistics regression for the binary outcome variable: "patient had 12-month visit (Y/N)".To consider the loss to follow up (patterns of visits), we separated the individuals into four different groups: (A) those individuals that did not come to any follow up visit, (B) those that came only to the 6-month visit, (C) those that came only to the 12-month visit, and (D) those that came to both follow up visits.

We described the absolute values of blood pressure (SBP and DBP), the proportion of patients with blood pressure under control and the distribution of hypertension stages for each of these groups in each of the visits. We estimated the average changes of blood pressure for each group at each follow up visit and we compared the changes between groups with Student's t-tests. We compared the mean of SBP and DBP between the groups with ANOVA models. To compare the proportion of patients with HT control or the distribution of hypertension stages between groups we used chi-square tests. To test the changes of variables within groups we used paired t-tests for continuous variables and marginal homogeneity tests for categorical variables.

Ethical Approval

Ethical approval was granted by the Institutional Review Boards (IRBs) of LSHTM (LSHTM Ethics Ref: 10,152), the Ghana Health Service (ID NO. GHS-ERC 04/01/15), and the University of Ghana at Noguchi Memorial Institute for Medical Research (Ethics clearance # IRB00001276). Written informed consent was obtained from all participants.

RESULTS:

Participants:

A total of 18,339 individuals 18 years and over were screened , 4118 referred to CVD nurses to confirm diagnosis, and of those 1339 were enrolled (76 (5.7%) low risk Grade 1 BP which is SBP 140 – 159 or DBP 90 – 99 without any target organ damages (TODs), co-morbidities or ≥ 2 risk factors), 559 (41.7%) (Moderate risk (SBP 160-179 or DBP 100 – 109 without any TODs, co-morbidities or ≥ 2 risk factors or Grade 1 BP with TODs, co-morbidities or ≥ 2 risk factors), and 704 (52.6%) High risk (Grade 3 which is SBP ≥ 180 or DBP ≥ 101 without any TODs, co-morbidities or ≥ 2 risk factors or Grade 2 BP with TODs, co-morbidities or ≥ 2 risk factors).

General characteristics of the cohort

The average age of the cohort was 58 years. Everyone was enrolled into the cohort by CVD nurses. Of the 1,339 people enrolled in the cohort, 24% were referred to ComHIP by LCS, 45% were referred by CHO, 23% were referred by CVD nurses, 3% were through physicians, and 5% were referred through other channels. 69% of the cohort was female, 31% male. Other characteristics of people enrolled in the cohort are found in Table 1.

Table 1. Characteristics of participants in the study at baseline.

Characteristic	% all	% 6 months	%12 months
Number	1339	552	338
Referred by			
LCS	23.9	23.4	24.3
CHO	45.0	40.8	38.5
CVD Nurse	23.3	25.4	26.9
Other	7.8	10.5	10.4
Sex			
Male	30.8	32.3	30.7
Female	69.2	67.8	69.3
Age class			
30-44	17.9	14.7	13.6
45-54	23.5	21.7	24.3
55-64	27.3	31.9	32.0
65+	31.4	31.7	30.2
Hypertension stage			
Normal	26.4	38.6	41.7
Stage I	39	39.9	39.4

Stage II	19.6	14.5	13.0
Stage III	14.9	7.1	5.9
Mean BP			
DBP	90.8	87.6	86.9
SBP	149.0	143.3	141.2
Education			
No formal education	37.0	32.3	31.4
Primary	41.7	431	45.6
Secondary	16.1	18.5	14.8
Higher	5.2	6.2	8.3
Ethnicity			
Akan	4.2	28.6	21.4
Dangme	69.5	42.2	26
Ewe	22	39.3	22.4
Other or don't know	4.3		
Religion			
Christian	96	97.6	97.9
Muslim	3.2	1.5	1.2
Traditional	0.5	0.4	0.3
None	0.3	0.5	0.6
Marital status			
Never married	5.7	5.1	3.6
Married/Cohabiting	54.4	54.7	57.7
Separated/Divorced	5.5	14.1	15.4
Widowed	26.1	25.9	23.1
No response	0.2	0.2	0.3
Household income			
Less than 728 GHC	18.7	17.0	17.2
728-1020 GHC	17.4	20.8	19.8
1021-1098	6.4	5.3	6.5
1099-1263	5.0	4.9	4.7
More than 1263 GHC	12.3	11.1	11.8
Don't know/no response	40.2	40.9	39.9
Aware of hypertension status			
Never had BP measured	18.7	17.6	16.3
Was not aware	12.9	11.4	10.7
Aware	68.5	70.8	73.1
Taking treatment			
Never diagnosed	31.5	29.2	26.9
Diagnosed and no treatment	18	15.0	16.0
Treatment	50.3	55.6	56.8
Don't know	0.2	0.2	0.3
BMI			
Underweight (BMI <18.5)	5.4	4.9	5.0
Normal weight (BMI 18.5-24.9)	43.7	44.8	43.2
Overweight (BMI 25-29.9)	29.2	30.1	32.5

Obese (BMI 30+)	21.7	20.3	19.2

*All patients with hypertension enrolled in cohort

**Patients with hypertension with six-month appointment/follow up

**Patients with hypertension with a twelve-month appointment/follow up

Other risk factors:

5.4% of the sample was underweight, 43.7% was normal, 29.2% was overweight and 21.7% was obese. The mean BMI at enrolment in the cohort was 26.1 (95% CI 25.82, 26.4).

We did not analyse smoking, cholesterol or diabetes as only 1% of the sample were smokers, 3.5% reported having had a previous cholesterol test, and only 28% had a previous diabetes test.

Blood Pressure at enrolment

The average SBP was 147.2 (SD 22.1) mmHg, and average DBP was 89.9 (SD 13.3) mmHg. At enrolment 917 (68.5%) had a previous diagnosis of hypertension, of which 654 (71.3%) were already taking some anti-hypertensives, and 297 (32.4%) had their blood pressure under control.

Blood pressure management

Of the 1339 enrolled in the study, 712 (53.2%) did not come for a follow up (group A), 289 (21.6%) had only a six-month visit (group B), 75 (5.6%) had only the 12-month visit (group C) and 263 (19.6%) had both visits (group D). In total only 552 (41%) had a six month follow up appointment, and only 338 (25%) had a 12 month follow up appointment.

Loss to follow up and Characteristics of those who stayed in the study

Patients with their hypertension already under control were more likely to present for care. The variable that showed the greatest association with likelihood of having a six or twelve-month appointment was enrolment month. Participants who enrolled earlier were much more likely to stay in the programme than those who enrolled later (Table 1)

Multivariate analysis suggested that recruitment before 12 May 2016 (one year before the break in service), age, education and hypertension under control in the first visit showed significant associations with having a twelve-month appointment. Recruitment after 12 May 2016 reduced the chances of coming to further visits, the older the patient and the higher the education level, the higher the chances that the patient would come to the follow up visits. Patients with controlled HT at enrolment were nearly twice as likely to come to follow up visits. None of the other variables showed significant associations (Table 2).

Table 2) multivariate analysis of baseline characteristics associated with staying in the programme 12 months

	OR	95% CI	P value
Enrolled year prior to break	0.46	(0.35, 0.60)	**0.00**
Sex	0.88	(0.63, 1.24)	0.48
Age (one year increments)	1.01	(1.00, 1.02)	**0.03**
BMI	1.00	(0.97, 1.02)	0.90
Edu. reference category: no formal education			
Primary education	1.41	(1.03, 1.93)	**0.03**
Secondary Education	1.13	(0.73, 1.73)	0.59
Higher education	2.42	(1.33, 4.43)	**0.004**
Reference cat: Never married			
Married/cohabitating	1.77	(0.90, 3.48)	0.10
Separated/Divorced	1.86	(0.90, 3.87)	0.10
Widowed	1.27	(0.61, 2.64)	0.52
Household size	1.01	(0.95, 1.07)	0.69
Hypertension control	1.93	(1.47, 2.54)	**<0.001**
Awareness of hypertension	1.00	(1.00, 1.00)	0.97
Hypertension treatment	1.00	(0.99, 1.00)	0.33
Any other previous diagnosis	0.86	(0.69, 1.07)	0.18
Confidence in management of hypertension	1.00	(1.00, 1.01)	0.63

Changes in Blood Pressure

Because 12 month follow up was below 30%, we did not look at overall changes in blood pressure, but we did look at overall changes in blood pressure in those that remained in the study at six and twelve months.

On average, patients who enrolled and presented for a follow-up appointment at around six months had a 10.3 mmHg reduction in SBP (95% CI -12.0,-8.6) and a 6.3mmHg reduction in DBP (95% CI -7.2, -5.2) (Table 3). There was a greater reduction in those patients who had a follow up appointment at one year, when there was a 12.2 mmHg reduction (95% CI -14.4, -10.1) in SBP and a 7.5 mmHg (95% CI 9.9, 6.1) reduction in DBP after one year in the programme. Not all patients who had a 12 month appointment also had a six month appointment, 263 had both, and they had am 11.9 mmHg reduction (95% CI -14.3, -9.5) in SBP and 7.1 reduction (95% CI -8.6, -5.5) in DBP (Table 3).

Knowledge of risk factors

Because of the poor retention, we were unable to comment on knowledge or risk factors.

Table-3) Changes in BP means and hypertension control by patterns of visits.

Groups	N	Vis.	SBP		DBP		HT Control
			Mean (SE)	Mean dif. (95%CI)	Mean (SE)	Mean dif. (95%CI)	% (95% CI)
All patients	1339	E	147.2 (0.60)		89.9 (0.36)		31% [29% , 34%]
	552	6m	132.9 (0.80)	-10.3 [-12.0 , -8.6]	81.3 (0.47)	-6.3 [-7.3 , -5.2]	69% [65% , 73%]
	338	12m	128.9 (1.05)	-12.2 [-14.4 , -10.1]	79.4 (0.61)	-7.5 [-8.9 , -6.1]	72% [67%, 77%]
(A) No visits	712	E	150.4 (0.85)		91.7 (0.49)		25% [21% , 28%]
(B) Only 6m	289	E	146.4 (1.28)		89.0 (0.77)		34% [29% , 40%]
		6m	135.7 (1.15)	-10.1 [-13.2 , -8.1]	82.7 (0.68)	-6.3 [-7.8 , -4.8]	61% [55% , 67%]*
(C) Only 12m	75	E	145.9 (2.62)		90.2 (1.63)		36% [25% , 48%]
		12m	132.5 (2.56)	-13.5 [-18.5 , -8.6]	81.0 (1.38)	-9.2 [-12.4 , -6.0]	71% [59% , 81%]*
(D) 6 & 12m	263	E	139.8 (1.18)		86.1 (0.80)		43% [37% , 50%]
		6m	129.8 (1.08)	-10.0 [-12.2 , -7.7]	79.8 (0.63)	-6.3 [-7.8 , -4.8]	77% [72% , 82%]*
		12m	127.9 (1.13)	-11.9 [-14.3 , -9.5]	79.0 (0.67)	-7.1 [-8.6 , -5.5]	72% [66% , 78%]*

* The comparison of these intervals with enrolment visit of the same group produce all p-values <0.0001

E= enrolment

There was also a significant reduction in hypertension stage, with a lower percentage of patients with hypertension having stage III hypertension over time (Table 4).

Table 4) Distribution of Hypertension Stage in each group in each visit.

The P-values are extracted from: (1) Chi-square tests to compare that row with group A of no follow-up. (2) from marginal homogeneity tests comparing the distribution of the same group in enrolment visit.

Groups by patterns of visits	N	Visit	No HT	Stage I	Stage II	Stage III	P-value
All patients	1,339	1m	31.0%	39.0%	18.4%	11.6%	
	552	6m	68.7%	19.7%	9.4%	2.2%	< 0.001 (2)
	338	12m	71.9%	19.5%	6.5%	2.1%	< 0.001 (2)
(A) No follow-up	712	1m	24.6%	38.7%	21.5%	15.2%	
(B) Only 6m visit	289	1m	34.3%	39.4%	17.0%	9.3%	0.002 (1)
	289	6m	60.9%	24.2%	12.1%	2.8%	<0.001 (2)
(C) Only 12m visit	75	1m	36.0%	36.0%	17.3%	10.7%	0.167 (1)
	75	12m	70.7%	14.7%	10.7%	4.0%	< 0.001 (2)
(D) 6 & 12m visit	263	1m	43.4%	40.3%	11.8%	4.5%	<0.001 (1)

	263	6m	77.2%	14.8%	6.5%	2.2%	< 0.001 (2)
	263	12m	72.3%	20.9%	5.3%	1.5%	< 0.001 (2)

Awareness

Overall awareness of hypertension status in the overall cohort was 68.5% at enrolment. Individuals who stayed in the programme longer, were more likely to be aware of their hypertension status. 70.8% of individuals who stayed in the programme for six months were aware of their hypertension status, and 73.1% of those who stayed in the programme for 12 months were aware of their hypertension status (Table 1).

Treatment

Treatment increased between enrolment and six and twelve-month appointments. Although only 44.2% of patients were receiving any medication at enrolment, the majority were being treated at six months (90.4%) and at 12 months (92.2%). At enrolment, the majority of patients who were on treatment were taking a calcium channel blocker (CCB) (36% of all patients), but at six months the majority were on diuretics (75.9%) followed by a CCB (69.5%). The same pattern was found at 12 months with 79.8% taking diuretics, and 71.5% taking a CCB (Table 5)

In patients who had a six-month appointment, 24.1% were taking only one medication, 32% were taking two medications, and over 30% were taking more than two medications. In patients who had a 12-month appointment, 23 % were taking one medication, 32.6% were taking two medications, and over 32% were taking more than two medications.

Table 5) treatment pattern in the cohort at enrolment, six months and 12 months with p-values for differences.

Treat	Enrolment	6 month	P change	12 months	P change
Diuretic	21.66%	75.89%	0.00000	79.83%	<0.00001
Calcium CB	36.07%	69.46%	0.00000	71.47%	<0.00001
Beta-blocker	3.14%	8.93%	0.00000	9.51%	0.00001
ACE inhibitor	6.72%	22.5%	0.00000	21.61%	<0.00001
ARB	2.54%	12.5%	0.00000	13.54%	<0.00001
Other	3.66%	15.89%	0.00000	17.87%	<0.00001
Any	44.29%	90.36%	0.00000	92.22%	<0.00001

0 medications	55.71%	9.64%	0.00000	7.78%	<0.00001
1 medications	19.42%	24.11%	0.21013	23.05%	0.62722
2 medications	20.46%	31.96%	0.00040	32.56%	0.00811
3 medications	4.18%	23.93%	0.00000	24.78%	<0.00001
4 medications	0.22%	6.96%	0.00000	8.07%	<0.00001
Mean	0.74	2.05	0.00000	2.14	<0.00001

Control

There was an increase in blood pressure control in patients who remained in the programme (Table 3), however patients who stayed in the programme were more likely to have their BP under control upon enrolment. In the group of patients that did not have a second appointment (group A) the baseline BP control was 25% while in the other groups (B, C, D) was 34%, 36% and 43% respectively. These differences were statistically significant (Table 4). The BP control increased to 69% (95% CI 65%-73%) in the individuals that visited at six months. In the patients that had the 12 month visit the control increased to 72% (95% CI 67%, 77%). Of patients who had both a six and 12-month follow-up appointment, the control increased to 77% (95% CI 72%-82%) at six months, but slightly decreased to 72% at 12 months (95% CI 66%-78%) (Table 3, Table 4).

DISCUSSION

Summary of results

Of the 1339 patients enrolled in ComHIP, only 552 (41%) had a follow up appointment at six months, and only 338 (25.2%) had a follow up appointment at twelve months, and 263 (20%) had both six and 12 month appointments Participants who had more education, were older, had their hypertension under control at enrolment, or who had the opportunity to spend at least a year in the programme before the break in service were more likely to attend appointments at six and/or twelve months.

Among the group of patients who continued in the programme for six or twelve months, we found strong evidence of a reduction in DBP and SBP, and an increase (from under half to more than two thirds) of hypertension control. We also found strong evidence of an increase of the patients under treatment, of the number of medications received per patient, and a decrease in the number of individuals with severe hypertension.

Comparison with other studies

Other studies evaluating task sharing for hypertension management have shown modest levels of success. For example, one randomised controlled study conducted in Ghana using task sharing (but with supplying free medications) showed greater reductions in SBP in patients randomised to the arm that included trained nurses, as compared to the one that just provided free medications and health insurance [11].

The poor follow-up reported in our study is not unexpected. Many studies have shown poor levels of follow up or adherence to clinic appointments. In one study conducted in three primary care clinics in Kibera, Kenya between 2010 and 2012, 1465 hypertensive or diabetic patients were identified. Of these 31% of patients were lost to follow up. Of these 55% of non-diabetic patients had their BP under control by 24 months, but only 28% of diabetic patients [12].

In another study conducted in Kibera, Kenya between 2015 and 2016, 3861 patients with hypertension were identified in health centres or clinics. of those 3069 patients did not complete six months of follow up (79%). Of those patients who remained in the programme over 6 months, they found 63% adherence to appointments [13].

In a study conducted in the slums of Nairobi only 3.4% of participants showed completed compliance with the programme. 30% only showed up for one appointment, and 5% only had two visits. Similar to our study they found that patients who remained in the programme showed significant reductions in SBP and DBP [14].

In a study done in two sites (one rural and one urban) in Malawi, of 4075 patients referred for clinical care, only 61% attended their referral appointments. Of those 47% of patients with hypertension were still in contact after 24 months. Similar to our findings, they found uptake in care to be higher in older patients, being on anti-hypertensives prior to enrolment, and not being in employment. Unlike our study, they found that females were more likely to be retained in care .[15]

Similarly, a study of hypertensive and diabetic patients in rural Cameroon found that only 18.1% of participants were still in care after one year. However similar to our study they found significant decreases in SBP and DBP in patients with hypertension with at least two documented visits.

Strengths and Limitations

A major strength of this study is unlike most other hypertension programmes ComHIP uses existing GHS protocols and medications and does not require outside funds or intervention for medications. This means that there is a much greater chance of long term sustainability of the programme as it does not rely on outside sources for medications.

Limitations of the study include that data were only available for encounters with service providers within the ComHIP network. Any appointments with doctors, pharmacists (licensed or un-licensed) that were not part of ComHIP would not have been registered, so it is possible that patients were obtaining anti-hypertensives from non-licensed sellers, which would not be captured in the ComHIP database. Another limitation of ComHIP was that the cohort did not have a control.

Due to the extremely poor follow-up, it is not possible to generalise our findings regarding the impact on blood pressure control to other studies, other than to emphasize the importance of effective strategies to promote follow-up. Finally, it is important to remember that nearly 70% of the initial cohort was aware of their hypertension status and about half were taking medications, which is a much higher proportion than in the general population. While this was done in ComHIP to ensure access to hypertension management to community members who otherwise would not have been able to access services, it is an important consideration when considering generalisability to the overall population.

Interpretation

In the 25% of people who had a 12-month appointment, there was strong evidence of an increase of the patients receiving medications, the average number of medications received per patient, and the level of hypertension control, we also found a reduction in both BP and hypertension status. However, like most other studies in the region, the high loss to follow up highlights that innovative hypertension programmes such as ComHIP need to develop better ways to retain patients within the programme.

Community based hypertension programmes in resource poor setting often are complex to carry out, and are prone to poor follow-up. There are many possible reasons that follow up in our study was low.

The factor most associated with retention in the programme was enrolment date. This is significant as due to operational issues, there was gap of CommCare utilization for three months. Anecdotally FHI 360 ComHIP staff learned that this gap in CommCare service had caused both service providers and staff to believe that the intervention had stopped, which may have resulted in a low rate of completion of follow-up appointments. Considering difficulties associated with community based studies in low resource settings, it is imperative to ensure continuity of service. Other factors that could cause this association may be health care professional fatigue; engaging patients to present for appointments may require considerable effort, such as multiple phone calls and personal interaction, for which the CVD nurses did not receive additional monetary compensation. It is possible that over time, the enthusiasm of the CVD nurses for the intervention may have waned. Also, as in any low – resource settings, there is a great deal of workforce turnover, FHI 360 recognised this early in the implementation and trained extra staff to bridge the gaps, however it is still possible that new health care providers who replaced them may not have had the same level of training. A complementary component of the evaluation which includes qualitative research with different ComHIP stakeholders is underway to analyse in depth the possible reasons that may have caused people to not adhere to the programme. (see Adler et al Barriers and facilitators to the implementation of a community-based hypertension improvement project in Ghana: A qualitative study and Laar et al Health system challenges to hypertension and related non-communicable diseases prevention and treatment: perspectives from Ghanaian stakeholders)

Lastly, our study found that older individuals were more likely to continue in care, this was found in at least one other study[15] but was not reported on in most studies. This could be because older patients may have more time to attend clinics. Patients with their hypertension under control were about twice as likely to stay in the programme. This is not surprising as they had already exhibited better health seeking behaviours.

Recommendations:

For patients enrolled and who continued in the programme we found an important impact on the management of hypertension and in blood pressure control. However, the high loss to follow-up of patients recruited limits the potential public health impact of these types of programmes. In order to minimize the impact of externalities (such as the CommCare service gap in ComHIP) programmes should have standard procedures and back-up systems to maximize the possibility that patients stay in the programme, particularly younger and less educated individuals. Also, appropriate incentives should be put in place to keep programme staff fully engaged and avoid programme fatigue. Future studies should further identify causes of loss to follow-up and find effective ways to adapt programmes accordingly (e.g. access to treatment within the community, targeted behaviour change messaging) to ensure that most of patients recruited stay long term in the programme. Future research may also want to focus on more difficult to reach patients who have lower levels of awareness and treatment on enrolment.

Acknowledgements
Funding for ComHIP was generously provided by the Novartis Foundation, Basel, Switzerland. We are grateful to all of cohort clients. We are also grateful to the leadership and political support of the Ghana Health Service (both from the national and district levels) for their support.

Competing interests
Co-authors PL, AKL, PP, AJA, and DP-M worked on the ComHIP Programme for which their institutions (LSHTM and UGSPH) have received grants from the Novartis Foundation. Co-authors RD, RD, and DM are staff of the FHI360, which provided technical direction to ComHIP implementation.

Authors' contributions
PL conceived of the project, PL and RD designed the interventions. PL, PP, AKL and AJA designed the research component of the project. DM, and RMMD supervised the implementation of the programme. RMMD is the programme data manager. AJA and DP-M performed the statistical analyses. AJA drafted the manuscript, with inputs from all authors. All authors read and approved the final version of the manuscript.

Consent to publish
Participants' consent was obtained for the purposes of publishing the results from the study. All the authors consented to the study results to be published in the form presented in the final version of this manuscript.

Data sharing
Summary statistics related to the dataset used in the project are available by request

Funding
Funds for the project was made available by Novartis Foundation, Basel, Switzerland. They did not have any input or control over this manuscript.

Figures

See attached supplementary file

REFERENCES

1. Collaborators, G., *Global, regional, and national disability-adjusted life-years (DALYs) for 333 diseases and injuries and healthy life expectancy (HALE) for 195 countries and territories, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016.* Lancet, 2017. **390**(10100): p. 1260-1344.
2. WHO, *World Health Organization-International Society of Hypertension Guidelines for the Management of Hypertension. Guidelines Subcommittee.* Am J Hypertens, 1999. **17**(2): p. 151–83.
3. Collaboration, B.P.L.T.T., *Effects of blood pressure lowering on cardiovascular risk according to baseline body-mass index: a meta-analysis of randomised trials.* The Lancet, 2015. **385**(9971): p. 867-874.

4. Collins, R., et al., *Blood pressure and coronary heart disease.* Lancet, 1990. **336**(8711): p. 370-1.
5. Law, M.R., J.K. Morris, and N.J. Wald, *Use of blood pressure lowering drugs in the prevention of cardiovascular disease: meta-analysis of 147 randomised trials in the context of expectations from prospective epidemiological studies.* Bmj, 2009. **338**: p. b1665.
6. Olsen, M.H., et al., *A call to action and a lifecourse strategy to address the global burden of raised blood pressure on current and future generations: the Lancet Commission on hypertension.* Lancet, 2016. **388**(10060): p. 2665-2712.
7. Addo, J., L. Smeeth, and D.A. Leon, *Hypertension in sub-saharan Africa: a systematic review.* Hypertension, 2007. **50**(6): p. 1012-8.
8. Chow, C.K., et al., *Prevalence, awareness, treatment, and control of hypertension in rural and urban communities in high-, middle-, and low-income countries.* Jama, 2013. **310**(9): p. 959-68.
9. Lamptey, P., et al., *Evaluation of a community-based hypertension improvement program (ComHIP) in Ghana: data from a baseline survey.* BMC Public Health, 2017. **17**(1): p. 368.
10. GSS, *Population by Region, District, Locality of Residence, Age Groups and Sex, 2010. Accra, Ghana: Ghana Statistical Service.* http://www.statsghana.gov.gh/docfiles/population_by_region_district_locality_of_residence_age_groups_and_sex,_2010.pdf. *Accessed November 22, 2016* 2012.
11. Ogedegbe, G., 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**(5): p. e1002561.
12. Sobry, A., et al., *Caseload, management and treatment outcomes of patients with hypertension and/or diabetes mellitus in a primary health care programme in an informal setting.* Trop Med Int Health, 2014. **19**(1): p. 47-57.
13. Kuria, N., et al., *Compliance to follow up and adherence to medication in hypertensive patients in an urban informal settlement in Kenya: comparison of three models of care.* Trop Med Int Health, 2018.
14. Werner, M.E., et al., *Results of a hypertension and diabetes treatment program in the slums of Nairobi: a retrospective cohort study.* BMC Health Services Research, 2015. **15**: p. 512.
15. Musicha, C., et al., *Accessing clinical services and retention in care following screening for hypertension and diabetes among Malawian adults: an urban/rural comparison.* J Hypertens, 2016. **34**(11): p. 2172-9.

Community-based Hypertension Improvement Project (COMHIP)

Clinical Guidelines

09.2015

SUMMARY

- This clinical guideline on the management of Hypertension is intended to promote evidence-based management of hypertension in the community and thereby improve patient's clinical outcomes.

- The guideline is intended to assist Licensed Chemical Sellers (LCS), Community Health Officers (CHOs), Cardiovascular Disease (CVD) Nurses and Physicians in the screening and diagnosis of HTN, determination of appropriate treatment, and delivery of individualized pharmacological and non-drug interventions.

- This guideline is general for the ComHIP project and individualized guidelines have been developed for the various service delivery personnel matching their responsibilities.

Table of Contents

1.0 PROJECT DESCRIPTION

- The community-based Hypertension Improvement Project (ComHIP), aims to improve hypertension management and control in Ghana. The project will test a community-based model that engages the private sector and utilizes information and communication technologies (ICTs) to enhance the capacity of the Ghana Health Service and individuals to control hypertension. There are four (4) categories of personnel (Figure 1) involved in service delivery in ComHIP. These are;

    - Community Health Officers
    - Licensed Chemical Sellers
    - Cardiovascular disease nurses
    - Physicians

- Community Health Officers (CHOs) will screen community members; Licensed Chemical Sellers (LCS) will screen clients and contribute to management and follow up of hypersensitive clients; cardiovascular nurses (CVD nurses) will be responsible for confirming hypertension diagnosis, grading and management of clients with mild and forms of hypertension; Physicians will be responsible mainly for managing severe hypertensive clients.

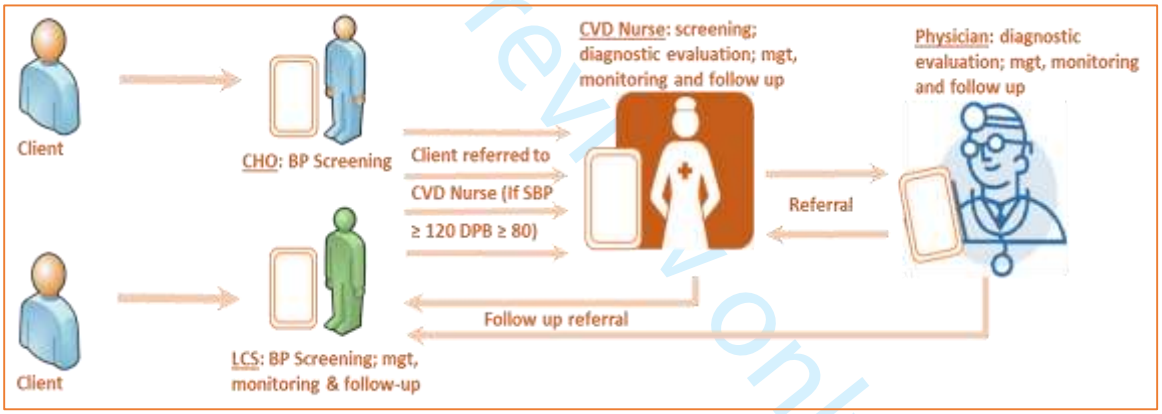


Figure 1: ComHIP Service delivery flow

- ComHIP involves the Ghana Health Service, FHI 360, London School of Hygiene and Tropical Medicine, University of Ghana School of Public Health, VOTO Mobile and with funding support from the Novartis Foundation. The project is for a period of 36 months.

2.0 SUMMARY OF PERSONNEL ROLE

Table 1 summarizes the various functions of licensed chemical sellers (LCS), community health officers (CHOs), cardiovascular disease nurses and Physicians working in ComHIP.

Table 1: Summary of roles of various service delivery personnel

Phase	Activity	Community Health Officer	Licensed Chemical Seller	CVD Nurse	Physician
Phase 1: Screening	Community BP screening	Yes	Yes	No	No
	Screening referral	Yes	Yes	No	No
Phase 2: Diagnostic Evaluation	Confirmation of BP (HTN) diagnosis	No	No	Yes	Yes
	Staging of degree of HTN	No	No	Yes	Yes
	Assessment of other CVD risk factors	No	No	Yes	Yes
	Assessment of prevailing CVD symptoms	No	No	Yes	Yes
	Overall risk assessment/ Stratification	No	No	Yes	Yes
	Assessment of family history of CVD	No	No	Yes	Yes
	Laboratory investigation	No	No	Yes	Yes
	Assessment of target organ complication	No	No	Yes	Yes
	Assessment of Lifestyle Issues	No	No	Yes	Yes
	Diagnostic referral	No	No	Yes	No
	Baseline Anthropometry	No	No	Yes	Yes
Phase 3: Management, Monitoring & Follow Up	Recommendation for drug treatment	No	No	Yes	Yes
	Medication Dispensing	No	Yes	No	No
	Recommendation for Non-drug treatment	Yes	Yes	Yes	Yes
	Evaluation of drug side effects	No	Yes	Yes	Yes
	Monitoring of BP response to treatment	No	Yes	Yes	Yes
	Adherence Counselling	No	Yes	Yes	Yes
	Anthropometric monitoring	No	No	Yes	Yes
	Regular follow up and interaction	No	No	Yes	No
	Management referral	No	No	Yes	Yes*

*In rare instances, certain patients may be referred by the Physician to a hypertension specialist

3.0 SCREENING

3.1 Hypertension Definition and Classification

Hypertension is used to refer to the level of blood pressure (BP) above which treatment does more good than harm. Numerically, hypertension is defined as a systolic blood pressure (SBP) ≥140 mmHg or a diastolic blood pressure (DBP) of ≥90 mmHg. The following BP classification has been adopted;

Table 2: Classification of blood pressure for adults aged ≥18years

BP Classification	Systolic BP (mmHg)		Diastolic BP (mmHg)
Normal	<120	and	<80
Pre-Hypertension*	120-139	or	80–89
Grade 1 Hypertension (Mild)	140–159	or	90-99
Grade 2 Hypertension (Moderate)	160–179	or	100–109
Grade 3 Hypertension (Severe)	≥180	or	≥110

*Pre-hypertension: This refers to patients with very real risk of developing chronic high blood pressure

3.2 BP Screening Protocol

A. Who should conduct screening? LCS, Community Health Officer (CHO)

B. Who is Eligible to be screened? Any adult in the community 18 years and older excluding pregnant women.

C. Where can Screening be done? LCS will conduct screening at their shops. CHOs will conduct screening at CHPS compounds and during outreach/home visits.

D. How should BP be measured? All personnel involved in ComHIP should adopt simple techniques that minimize BP measurement errors: The following are recommended;

i. Ensure a quiet environment
ii. Patient must be rested for at least 5minutes, quiet and comfortable.
iii. Patient must be seated with arm at heart level and feet flat on the floor
iv. Ensure that sleeves are rolled up or any tight clothing removed.
v. Ensure that the individual has not exercised, smoked or consumed foods, alcohol or drinks containing caffeine (such as tea or coffee) at least 30 minutes before measurements
vi. Ensure that client is not acutely ill or injured
vii. Use appropriate size cuff (E.g. too small a cuff can raise BP)
viii. Measure BP in both arms at first; then subsequently only measure in the arm which gave the higher reading.
ix. Each time BP is to be measured, 3 readings must be taken at least 3minutes apart.
x. Refer to BP measurement guide whenever unsure.

E. What to do with BP reading?

I. All clients with BP ≥140/90mmHg must be referred to CVD nurse. Clients with BP in the Pre-hypertension range must be counselled on lifestyle and encourage to check BP regularly.
II. For clients with BP≥180/110 stress the need for urgent/immediate visit to a CVD nurse and arrange this visit with the CVD nurse.

⌧ Remember to explain to client that Screening is not diagnosis. Further investigation would be needed even if you suspect that the high BP may be hypertension.

4.0 DIAGNOSIS AND EVALUATION

4.1 Objectives of diagnostic evaluation

There are four key objectives in the assessment of a person with suspected hypertension are;

1) To confirm whether or not blood pressure is elevated
2) To document the presence or absence of blood pressure related target organ damage (e.g. left ventricular hypertrophy, hypertensive retinopathy, increased albumin: creatinine ratio);
3) To evaluate the person's cardiovascular risk either due to established cardiovascular disease or high cardiovascular disease risk states (e.g. diabetes or CKD), or by calculation of their 10 year CVD risk estimate
4) To consider whether there may be secondary causes for the hypertension.

4.2 Confirmation of hypertension diagnosis

A. Who should confirm HTN diagnosis? For most cases CVD nurse would confirm hypertension status and grade severity. In few instances, Physicians would do this for referred clients.

B. How should BP (HTN) be confirmed? The Following steps are recommended Use two measurements obtained two weeks apart.

i. At each visit, take 3 BP readings and record the mean
ii. Systolic equal or greater than 140 and or diastolic equal or greater than 90 (use mean of the readings obtained at the three separate visits)
iii. For clients with initial BP in grade 3, CVD nurse must provide immediate starting dose and refer to physician

4.3 Grading of the Severity of Hypertension

A. Who should grade severity of hypertension? Usually CVD nurse will be responsible for grading patients, Physicians will confirm severe hypertension grade.

B. How should HTN severity be graded? Use Table 2 (page 6) to grade level of severity.

C. Are there any referrals needed?

I. YES, CVD nurse must refer all patients with severe hypertension to a Physician.

⌦ All confirmed patients 18-30yrs must be referred for further investigation by a physician to rule out possible secondary causes.

4.4 Assessment for other CVD risk factors

A. Who should conduct assessment of CVD risk factors? CVD nurse, Physician

B. **How should CVD risk factors be assessed?** A set of questions are useful in assessing CVD risk factors. Usually a Yes or No response is required from clients by asking the following;

i. Have you had prior history of diabetes or hypertension?
ii. Have you had prior history of elevated serum lipids
iii. Do you currently smoke tobacco on a daily basis, less than daily, or not at all?
iv. In a typical week, how many minutes do you spend engaging in vigorous/high intensity physical work, activities or exercises?
v. Do you drink alcohol?
vi. Have you had prior history of high cholesterol

4.5 Assessment for Target Organ Damage or CVD Event

A. Who should conduct assessment for TOD/CVD events? CVD nurse, Physician

B. How should TOD/CVD event assessment be done? A yes or No responses are usually needed from patients upon asking the following questions;

i. Have you had prior history of heart failure
ii. Have you had prior history of heart attack
iii. Have you had prior history of a stroke or Transient Ischemic Attack (Mini stroke)
iv. Have you had prior history of kidney failure or disease

4.6 Assessment of Family History

A. Who should conduct assessment of family history? CVD nurse, Physician

B. How should family history assessment be done? Enquire from patient about history of any CVD event (stroke, heart attack) in parents and siblings; especially at age of less than 50.

4.7 Assessment of ongoing CVD symptoms

A. Who should conduct assessment of prevailing CVD symptoms? CVD nurse, Physician

B. How should ongoing CVD symptoms be assessed? Enquire from patient to obtain a Yes or No answer using set of questions below;

i. Ask about exertional dyspnea or at rest
ii. Ask about sleep disturbance by shortness of breath
iii. Ask about sleeping with more pillows of preference to sleep in a chair
iv. Ask about cough or wheezing during sleep.
v. Ask about excessive tiredness.
vi. Ask about central severe chest pain that disables the patient.
vii. Ask about feeling weak or wanting to faint
viii. Ask about palpitations
ix. Ask about loss of consciousness, vision, or speech.
x. Ask about weakness or numbness of one side of the body.
xi. Ask about swelling of feet and legs.

4.8 Anthropometric assessment

A. Who should conduct anthropometric measurements? CVD nurse, Physician

B. What anthropometric measurements should be assessed? Weight, Height, Waist Girth. Calculate BMI

C. When should measurements be taken? Obtain accurate measurements during enrollment, thereafter every three months.

D. How should anthropometric measurements be conducted? Follow recommended techniques below for each assessment;

4.81 Weight

This should be measured using a weighing scale. Follow the following steps;

I. Before each measurement, make sure the scale is zero
II. Ask the patient to remove heavy outer clothing (e.g. coats, jackets, shoes etc.)
III. Ask the patient to stand motionless in the middle of the scale platform with the feet slightly apart and the body weight distributed equally on both feet.
IV. Record body mass to nearest 0.1 Kg
V. Ask patient to step off scale

VI. Repeat steps
VII. If the 2 measurements differ by more than 0.4 kg then repeat steps one more
VIII. If two measurement record the average value. If three measurements record the median value.
IX. Refer to Weight measurement guide

4.82 Height

This should be measured using a Stadiometer. Follow the following steps;

- Ask the subject to stand on the centre of the base with their back to the stadiometer
- Ask them to put their feet together and move back until their heels touch the bottom of the stadiometer upright.
- Their buttocks and upper part of their back should also be touching the stadiometer upright. Their head does not have to touch the stadiometer.
- The respondent's head should be in the Frankfort plane.
- This is achieved when the lower edge of the eye socket (the Orbitale) is horizontal with the Tragion [see appendix 5.5].
- The vertex will be the highest point on their head. If their head is not aligned properly, (and for most respondents it probably won't be), ask them to raise or lower their chin until it is in the Frankfort Plane.
- When you are happy that the respondent is in the correct position, ask them to take a deep breath and hold it.
- Lower the headboard until it is in contact with the head. Compress the hair if needed. Make sure you don't bend the headboard from the horizontal, nor move the respondent's head.
- Hold the headboard firmly at its final position and take the reading to the nearest 0.1 cm.
- When you have completed the reading, ask the respondent to step away from the stadiometer.
- Record measurements immediately.
- Refer to height measurement guide for more details

4.83 Waist Circumference

This should be measured using a tape measure. Follow the following steps;

- Ask the patient to place himself in the following manner: Clear the abdominal region, Feet shoulder-width apart, Arms crossed over the chest
- It is suggested to kneel down to the right of the patient in order to measure waist girth; palpate the patient's hips to locate the top of the iliac crest and Draw a horizontal line halfway between the patient's back and abdomen**.**
- Place the measuring tape horizontally around the patient's abdomen. To work comfortably, it is suggested to wrap the tape around the patient's legs and then move it up.
- Align the bottom edge of the tape with your marked point. Gently tighten the tape around the patient's abdomen without depressing the skin.
- It is suggested to request the patient to relax and breathe normally (abdominal muscles should not be contracted). Ask the patient to take 2 or 3 normal breaths. Measure from the zero line of the tape (to the nearest millimetre) at the end of a normal expiration

4.9 Assessment for signs of CVD

A. Who should conduct assessment for signs of CVD? CVD nurse, Physician

B. How should assessment for signs of CVD be conducted?

i. Note a significant difference (>15mmHg) systolic BP in the arms (Nurse & Physician)
ii. Listen to the neck for bruits (Physician)
iii. Feel for irregularity of the radial pulse; also for rates greater than 100bpm. (Nurse & Physician)
iv. Check for displacement of the apex beat. (Physician)
v. Listen to the heart for normal and abnormal sounds (Physician)
vi. Listen to the back of the chest for Crepitation (Physician)
vii. Look and feel for swelling of the legs and feet (Nurse & Physician)

4.10 Risk stratification

A. Who should conduct overall risk assessment/stratification? CVD nurse, Physician

B. What are the general considerations to grade overall risk? Make consideration of the following in grading overall patient risk.

i. Consider the severity of the hypertension (Refer to table 3 below)
ii. Consider the other CVD risk factors of the patient
iii. Consider any target organ damage*

Table 3: Grading of blood pressure values

BP ranges	Pre-Hypertension		Grade 1	Grade 2	Grade 3
	Normal SPB 120–129 DBP 80–84	High normal SPB 130–139 DPB 85–89	SPB 140–159 DPB 90–99	SPB 160–179 DBP 100–109	SBP ≥180 DBP ≥110

⌦ Risk Factors

The following risk factors are included in the risk stratification.

- Men aged >55 years
- Women aged >65 years
- Smoking
- Dyslipidemia
- Family history of premature cardiovascular disease (men aged <55 years, women aged<65 years)
- Abdominal obesity (abdominal circumference ≥102 cm for men, ≥88 cm for women)

⌦ Comorbidities

The following conditions are included where possible in the overall risk assessment;

- Cerebrovascular disease (TIA, stroke) (Nurse & Physician)
- Heart disease (angina, myocardial infarction, heart failure) (Nurse & Physician)
- Chronic renal disease (Nurse & Physician)
- Peripheral vascular disease (Physician)
- Diabetes (Nurse, Physician)

Table 4: CVD Risk stratification for patients

High Risk	• Grade 3 BP, with or without TOD, risk factors and Comorbidities • Grade 2 BP with TOD and/or +2 risk factors
Moderate risk	• Grade 2 BP without TOD, >2 risk factor or comorbidities • Grade 1 with TOD and/or >2 risk factors, comorbidities
Low risk	• Grade1 BP with no TOD, risk factors or co-morbidities

***TOD** is used to refer to damage occurring in major organs fed by the circulatory system (heart, kidneys, brain, eyes) which can sustain damage due to uncontrolled hypertension. TOD will be assessed by history, physical examination and laboratory investigation. However, TOD will mainly be clinically determined as this will be the usual or expected level of care in the study area. Specific TODs will be assessed as below;

a) Heart Failure criteria for assessment;
- paroxysmal nocturnal dyspnea
- orthopnea
- nocturnal cough or wheezing
- sinus tachycardia
- leg and pedal edema
- Objective tests : ECG evidence of left ventricular hypertrophy (LVH)

b) Kidney damage:
- To be assessed with tests- proteinuria and serum creatinine or prior diagnosis of same. Subjective symptoms: Polyuria, nocturia, haematuria

c) Brain damage:
- To be clinically assessed- symptoms of stroke or prior documentation of a stroke.

d) Eye damage
- Examine the fundi for the presence of hypertensive retinopathy. Subjective signs: impaired vision

4.11 Laboratory Investigations

A. Who can order for laboratory investigation? CVD nurse, Physician

B. What laboratory investigations are recommended?
- Physician should prioritize the following investigations;
  I. Complete blood count
  II. Fasting sugar, HbA1c, and lipids
  III. Urinalysis
  IV. Renal profile.
  V. Electrocardiogram **(**ECG)
- CVD nurse should prioritize the following investigations;
  I. ECG
  II. Fasting blood sugar

C. Laboratory prioritization for different risk profiles
- Low Risk: ECG (Nurse)
- Moderate risk: Glucometer FBS,ECG (Nurse)
- High risk: Full range (Physician)

5.0 MANAGEMENT, MONITORING AND FOLLOW UP

5.1 BP Treatment Goal

A. Who should outline BP treatment goal? CVD nurse, Physician

B. What BP treatment goal should be set for a patient? The goal of treatment is to bring all patients to below 140/90mmHg

5.2 Recommendations for Non-drug Treatment

A. Who should make recommendations for non-drug treatment? CVD nurse and Physicians should make recommendations, LCS should reinforce such recommendations

B. Who are the candidates for non-drug treatment? Non-drug measures should be recommended for all clients diagnosed as pre-hypertensive and hypertensive.

C. What non-drug approaches should be recommended? Prioritize the following;

i. Maintenance of Ideal body Weight
ii. Healthy low salt and Low fat diet
iii. Increased fruit and vegetable consumption
iv. No more than two drinks a day
v. No smoking
vi. Regular aerobic exercise; simple daily brisk walk for thirty minutes
vii. Adequate management of stress and anxiety levels

5.3 Recommendation for drug treatment

A. Who should make recommendations for drug treatment? CVD nurse, Physician

B. Which clients are candidates for drug therapy? All enrolled clients (BP ≥140/90mmHg) are candidates for drug therapy supplemented with lifestyle modification irrespective of risk level.

C. Should treatment be initiated with monotherapy or multiple drugs? The decision to begin with a single or dual drugs rests principally on the level at which the clients BP is above goal and on patients overall risk profile. Typically;

i. Begin with a SINGLE drug if BP<20/10mmHg above goal and in low risk patients.
ii. Begin with TWO drugs if BP>20/10mmHg above goal and in moderate and high risk patients.

5.4 Types of Antihypertensive drugs

A. What are the main drugs that can be prescribed? Four (4) drugs are recommended to CVD nurses for starting treatment in eligible patients in the ComHIP study. Physicians will have wider options to address complex patients' needs. The recommended drugs are;

I. Diuretic: Bendroflumethiazide. –initial dose, 2.5mg daily. Maximum dose of 5mg daily.
II. Beta-blocker: Atenolol-initial dose of 50mg daily. Maximum dose of 100mg daily provided the heart rate is greater than 60/min on the lower dose.
III. Calcium channel blocker: Nifedipine retarde or XL -initial dose 30mg daily. Maximum dose of 60 to 90 mg daily.
IV. ACE Inhibitor: Lisinopril-initial dose of 20mg daily. Maximum dose of 30mg daily.

5.5 Titration of antihypertensive medications (CVD Nurses): Low and Moderate risk patients

- The following steps should guide CVD nurses in the dose titration of hypertensive medications;

A. Patients with a difference between enrollment and goal BP that is less than 20/10mmHg

- Start with only bendrofluomethiazide. (See Appendix 7.2)
- Add atenolol or nifedipine or Lisinopril if BP is greater than goal of 140/90 after three months of bendrofluomethiazide.
- Wait for three more months and if BP is still greater than 140/90, increase the dosage of the atenolol or nifedipine or Lisinopril.
- Wait for another three months and refer patient to a physician if BP is still greater than 140/90

- Key point: For clients with BP<20/10 above goal, typically they will undergo 9months of therapy after which failure to attain BP goal will call for referral to a physician at hospital. However, referral may be made anytime if any complication or serious adverse effects occur within this 9-month period. Patient monitoring should be done every 6weeks irrespective of whether change in therapy or not.

B. Patients with a difference between enrollment and goal BP that is greater than 20/10

- Start with bendro AND atenolol or nifedipine or Lisinopril
- After three months if BP is greater than 140/90, increase the dosage of the atenolol or nifedipine or Lisinopril.
- If BP remains greater than 140/90 three months later, then refer to physician.

- Key point: For clients with BP≥20/10 above goal, typically they will undergo 6months of therapy after which failure to attain BP goal will call for referral to a physician at hospital. However, referral may be made anytime if any complication or serious adverse effects occur within this 9-month period. Patient monitoring should be done every 6weeks irrespective of whether change in therapy or not.

5.6 Titration of antihypertensive medications (Physicians): High risk patients

- The following steps should guide physicians in the selection and dose titration of hypertensive medications.

A. What drugs are available to physicians? All the classes of antihypertensive below;

a) Diuretic: bendroflumethiazide.-2.5mg daily
b) Calcium Channel Blocker (CCB): Amlodipine 5-10mg or Nifedipine (SR) 20-60mg daily
c) Beta Blocker: Atenolol 50-100mg daily
d) Angiotensin Converting Enzyme (ACE) Inhibitor: Lisinopril 10-30mg daily
e) ARB: Losartan 50-100mg daily

- Additional options like centrally acting agents, alpha blockers, aldosterone antagonist may be available to physicians

B. What are the acceptable and possible combinations? The possible combinations are a+b; a+c; a+d; a+e; b+d; b+c; b+e

- The choice may be influenced by the presence of the patient's other medical conditions
- Titrate dose or add additional drug to lower the BP to goal.

C. Recommendations for compelling indications

There is evidence to support the use or avoidance of certain antihypertensive when other conditions are present. These include the following;

Table 5: Compelling indications for individual drug classes

compelling indications	initial therapy options
Heart Failure	THIAZ, BB, ACEI, ARB, ALDO ANT
Post Myocardial Infarction	BB, ACEI, ALDO ANT
High CVD risk	THIAZ, BB, ACEI, CCB
Diabetes	THIAZ, BB, ACEI, ARB, CCB
Chronic Kidney Disease	ACEI, ARB
Recurrent Stroke Prevention	THIAZ,ACEI

Keys: THIAZ=thiazide diuretic, ACEI=angiotensin converting enzyme inhibitors, ARB=angiotensin receptor blocker, BB=Beta-blocker, CCB=calcium channel blocker, ALDO ANT=aldosterone antagonist

5.7 General Prescribing Guideline

A. Who should prescribe antihypertensive medicines? CVD Nurse, Physician

B. Before prescribing medicines confirm that patient agrees to be on medications

C. How should prescriptions be written? Follow the steps below;

i. written legibly in ink or otherwise so as to be indelible
ii. written by the prescriber (CVD Nurse, Physician) and not left for someone to complete
iii. should be dated
iv. The full name and address of the patient should be stated
v. Dosage form, generic name of medication, strength, dose and dosage schedule
vi. Exact quantity of medication to be supplied
vii. the signature of the prescriber(CVD nurse, Physician) (which should be in ink)

5.8 Side Effect Monitoring

A. Who should monitor side effects in patients? CVD nurse, LCS, Physician

B. What are the possible side effects of various medicines? See below;

i. ACE Inhibitors: swelling of lips, tongue and throat; the patient must be advised to seek immediate medical help. They can cause irritating dry cough.
ii. Beta blockers: worsening or precipitation of asthma; bradycardia; worsening of HF
iii. Calcium channel blockers: edema of the feet
iv. Diuretic: low potassium leading to generalized weakness.

5.9 monitoring of response to treatment

A. Who should monitor clients' response to treatment? CVD nurse, Physician, LCS

B. What should be the monitoring priorities? see key focus below

i. Aim for goal BP reading
ii. Monitor for side effects
iii. Check for adherence to the non-drug measures for BP control
iv. For resistant hypertension consider evaluation for interfering substances
v. Also consider specialty consultation for patients with resistant hypertension.

5.10 General dispensing Guideline (For LCS only)

A. Who should dispense medication? LCS

B. What checks should be done before dispensing medicines? LCS should ensure that;

i. the prescription is legally valid, genuine and has not been altered after issuing
ii. Each medicine on the prescription contain the dosage form, generic name, strength, dose, dosage schedule and quantity of medication to be supplied
iii. The prescription is assessed for validity, safety and clinical appropriateness.

C. How should medicines be labelled? Each dispensed medication should be appropriately packaged and adequately labelled with the following minimum information:

i. Name of the patient and the generic name of the medicine
ii. Strength of the active ingredient and special instructions
iii. Quantity of dispensed product
iv. Complete dose regimen in written and/or graphic form
v. Duration of use
vi. Name and address of the LCS facility and dispenser
vii. Date of dispensing

⊠ Dispenser should always ensure that patient fully understands how the medication should be taken before leaving premises.

5.11 Hypertensive Emergencies

⊠ Severe hypertension, usually BP>180/110 mmHg in adults may be associated with acute neurological, cardiovascular or renal compromise, and could be fatal.

- If an LCS or CHO records BP reading for a client in this range, arrangements must be made immediately to see a CVD nurse must immediately administer oral hydralazine 10mg and refer to a physician. Arrange with the physician for the patient's visit
- Physician to administer hydralazine IV 5-10 mg slowly over 20 minutes. This dose may be repeated after 20-30minutes, until the patient is conscious and can take oral medications.

5.12 Referral SOP for CVD nurse

A. Mild/Moderate risk Patients

- All confirmed hypertensive clients' 18-30years should be referred to a physician for further investigation.
- All clients with suspected secondary causes should be referred to a Physician
- All mild and moderate hypertensive clients with no change in BP levels within the first 90 days (resistant hypertension) of treatment should be referred to a physician.
- Clients who have developed intolerable side effects should be referred
- All clients who develop hypertension-related complication should be referred to a physician
- All clients who show signs of target organ damage while under treatment should be referred to a physician.
- Any client who experiences a cardiovascular event while under treatment should be referred to a physician

B. High risk Patients

- All severe/high risk patients should be referred to a physician
- All clients with history of unstable stroke or cardiovascular event should be referred to a physician

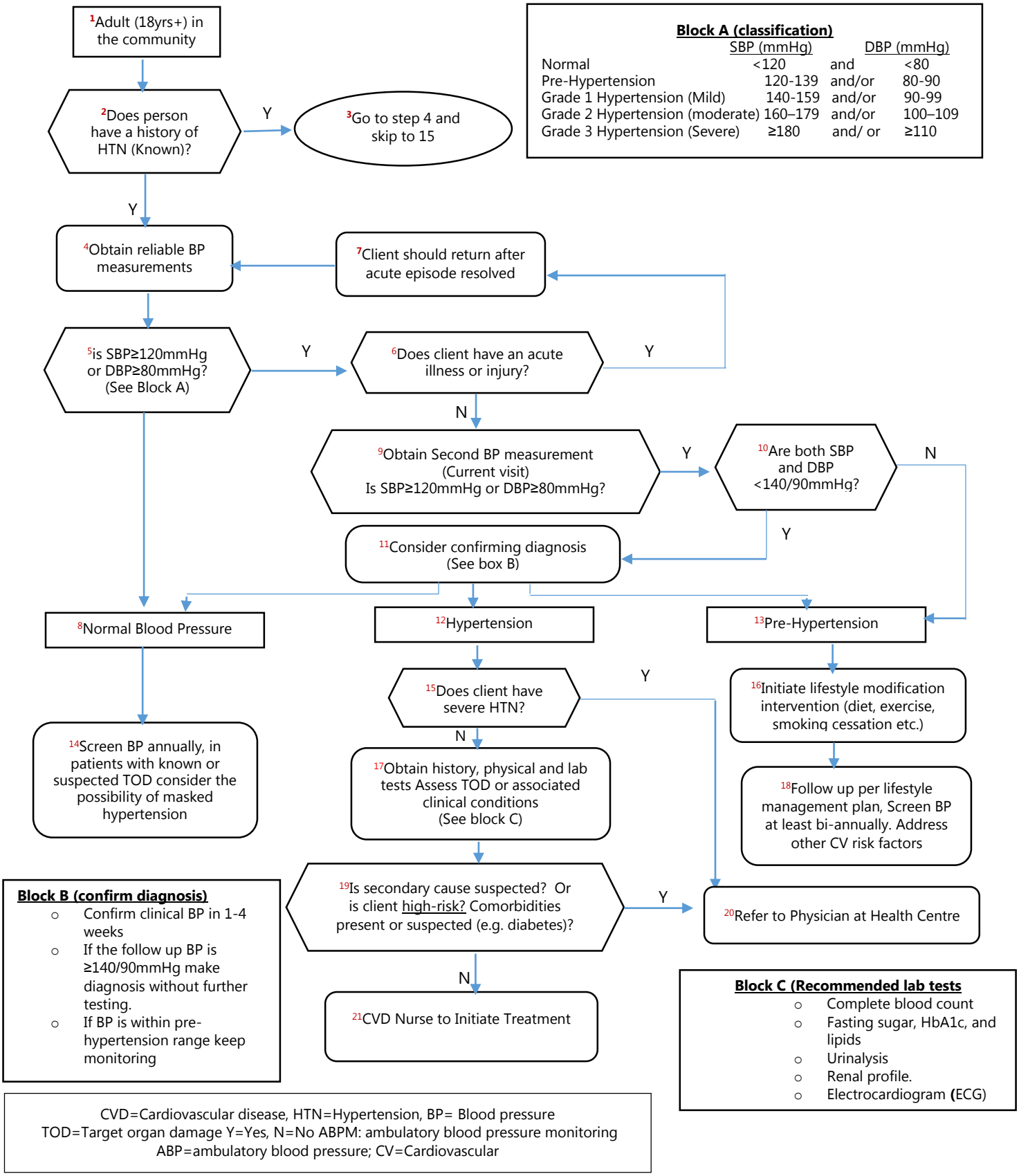
5.13 Proposed activities for patients' visit

The following is aimed at helping CVD nurses determine what needs to be done at a patients visit.

Table 6: Patient Visits and proposed activities

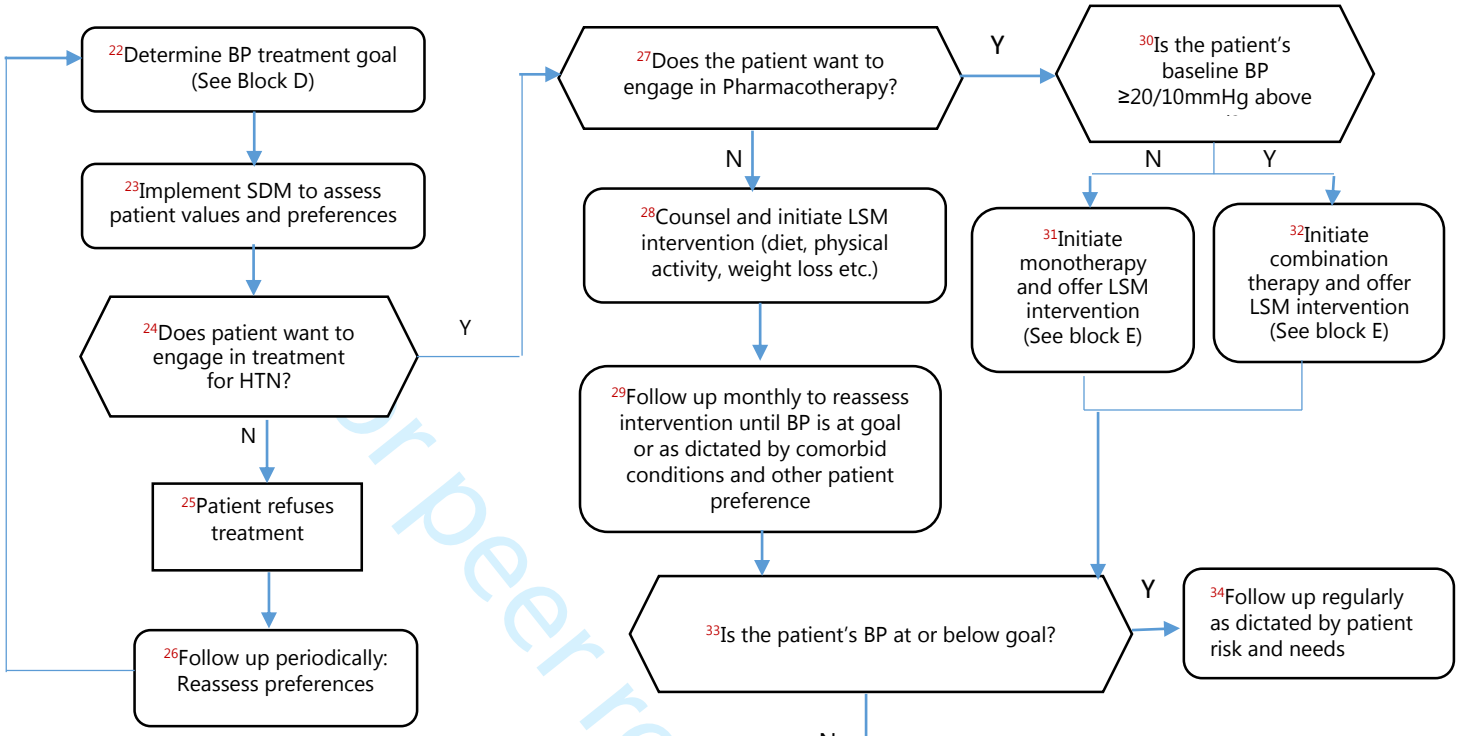
Visit Number	When	Activity
1	After patient has been screened and referred by LCS, CHO	CVD Nurse to recheck BP
2	Two weeks after visit 1	1. CVD Nurse to recheck BP and confirm diagnosis 2. Enroll patient, perform risk assessment, perform anthropometric measurements 3. Refer to Referral SOP for CVD nurse for all patients that should be referred to Physician. 4. Initiate treatment 5. Order laboratory investigation as needed 6. Perform Hypertension counseling
3	6 weeks after visit 2	1. Re-check BP 2. Assess treatment, perform counseling
4	6 weeks after visit 3	1. Review treatment plan until goal is reached 2. Perform anthropometric measurements every 3 months after enrollment
5 & subsequent visits	• Every 3 months for patients with Mild Hypertension (treated by CVD nurse) • Every 2 months for patient with Moderate Hypertension (treated by CVD nurse) • Monthly for Patients with High (treated by Physicians only)	1. Re-check BP, review treatment, assess for risk factors, perform Hypertension counseling 2. Conduct follow up assessment every 6 months after enrollment

6.0 SCREENING AND DIAGNOSIS ALGORITHM



CVD=Cardiovascular disease, HTN=Hypertension, BP= Blood pressure
TOD=Target organ damage Y=Yes, N=No ABPM: ambulatory blood pressure monitoring
ABP=ambulatory blood pressure; CV=Cardiovascular

7.0 MANAGEMENT FLOW ALGORITHM



Block D (Treatment Goals)

- Goal is to bring BP to 140/90mmHg or below
- In Diabetics the aim is 130/80mmHg or below

Block E (Initiate Drug Therapy)

- 1st Line: Thiazide-type diuretics
- 2nd Line: ACEIs, ARBs, CCBs, Long-acting DHP
- 3rd Line: Aldosterone antagonist or Potassium-sparing diuretic or Alpha-blocker or Beta-blocker

Block F (Optimize management)

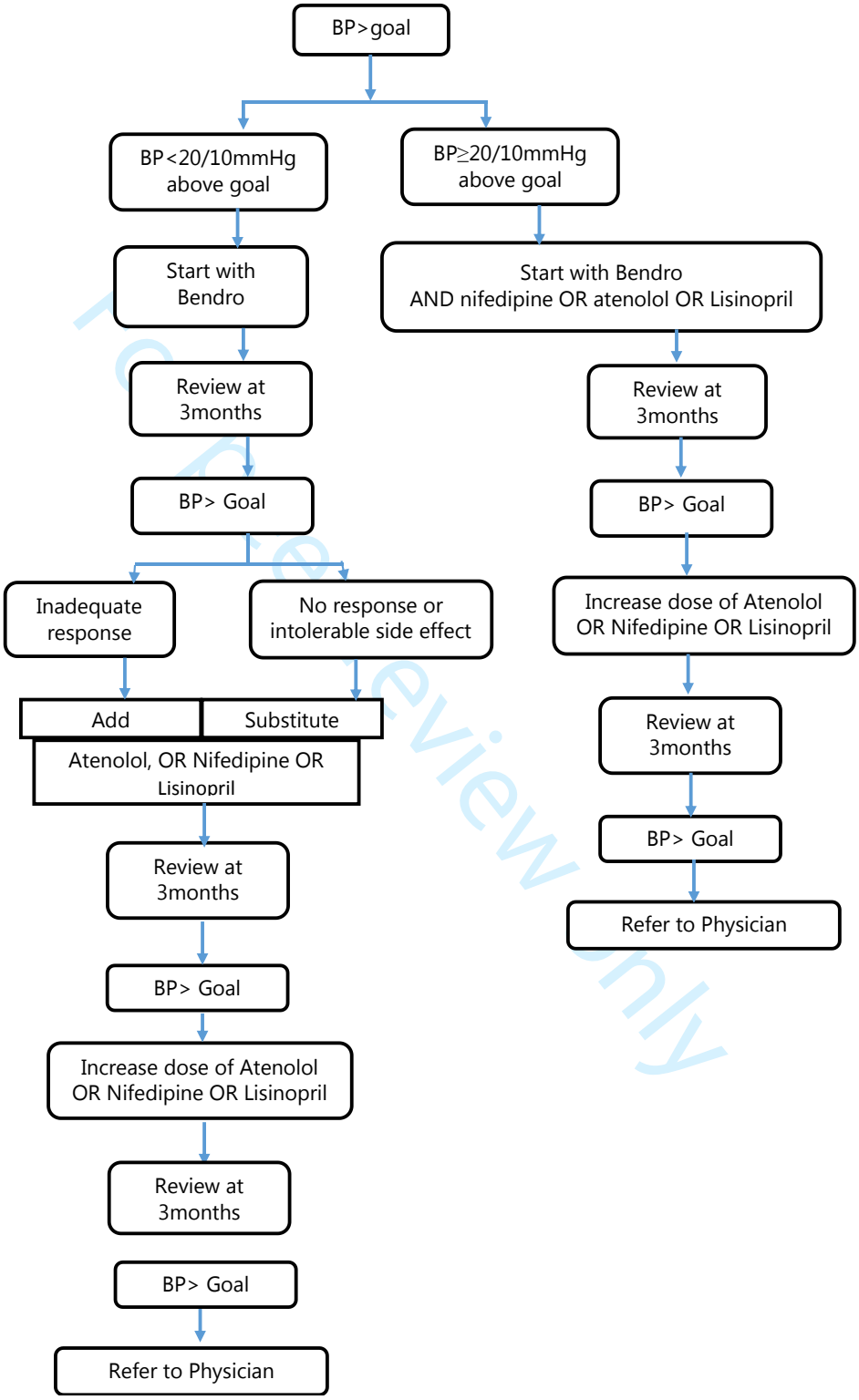
- Optimize treatment
  - Titrate initial drug (s)
  - Add another agent from different class
- Assess adherence
- Reevaluate diagnosis (resistant HTN)
  - Consider evaluation for interfering substances or contributing secondary causes of hypertension
  - Consider specialty consultation for patients with resistant hypertension

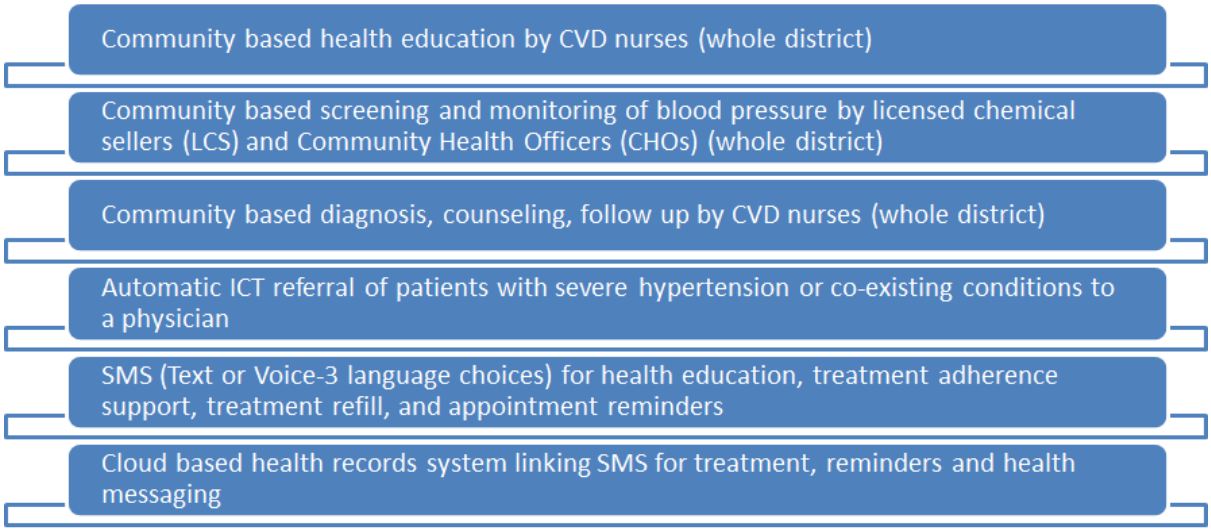
7.0 APPENDIX

7.1 Summary of GHS and NHIA approved drugs

Class	Medicine	Recommended in GHS treatment guideline	Available on NHIS Medicines List	Reimbursement NHIA cost (GHC)
Diuretics	Bendroflumethiazide 2.5mg	Yes	Yes	0.06/tab
	Bendroflumethiazide 5mg	No	Yes	0.06/tab
	Spironolactone 25mg	No	Yes	0.40/tab
	Spironolactone 50mg	No	Yes	0.70/tab
Beta-Blockers	Atenolol 25mg	Yes	Yes	0.10/tab
	Atenolol 50mg	Yes	Yes	0.10/tab
	Atenolol 100mg	Yes	Yes	0.13/tab
	Bisoprolol	Yes	No	n.a
	Carvedilol	Yes	No	n.a
ACE inhibitors	Lisinopril 2.5mg	Yes	Yes	0.18/tab
	Lisinopril 5mg	Yes	Yes	0.20/tab
	Lisinopril 10mg	Yes	Yes	0.25/tab
	Lisinopril 20mg	Yes	Yes	0.30/tab
	Ramipril 2.5mg	Yes	Yes	0.22/tab
	Ramipril 5mg	Yes	Yes	0.40/tab
ARBs	Losartan 25mg	Yes	Yes	0.36/tab
	Losartan 50mg	Yes	Yes	0.50/tab
	Losartan 100mg	Yes	Yes	1.0/tab
	Candesartan	Yes	No	n.a
	Valsartan	Yes	No	n.a
Calcium Channel Blockers	Nifedipine 10mg (capsule)	No	Yes	0.35/cap
	Nifedipine 10mg (SR)	Yes	Yes	0.21/tab
	Nifedipine 20mg (SR)	Yes	Yes	0.17/tab
	Nifedipine 30mg XL (GITS)	Yes	Yes	0.47/tab
	Amlodipine 5mg	Yes	Yes	0.20/tab
	Amlodipine 10mg	Yes	Yes	0.30/tab
Alpha Blockers	Prazosin 500mcg	Yes	Yes	0.60/tab
Centrally acting agents	Methyldopa 250mg	Yes	Yes	0.25/tab
Vasodilators	Hydralazine 25mg	Yes	Yes	0.70/tab
Combination therapies	Atenolol + Hydrochlorothiazide (50+25mg)	No	Yes	1.00/tab
	Atenolol + Hydrochlorothiazide (100mg +25mg)	No	Yes	2.10/tab
	Lisinopril + Hydrochlorothiazide (10mg+12.5mg)	No	Yes	1.00/tab
	Lisinopril + Hydrochlorothiazide (20mg+12.5mg)	No	Yes	2.05/tab

7.2 Drug Management Flow diagram for CVD nurses





Supplementary figure 1) components of the ComHIP Programme

Visit Number	When?	Activity
1	After patient has been screened and referred by LCS, CHO	CVD Nurse to recheck BP
2	Two weeks after visit 1	1. CVD Nurse to recheck BP and confirm diagnosis 2. Enroll patient, perform risk assessment, perform anthropometric measurements 3. Refer to *Referral SOP for CVD nurse* for all patients that should be referred to Physician. 4. Initiate treatment 5. Order laboratory investigation as needed 6. Perform Hypertension counseling
3	6 weeks after visit 2	1. Re-check BP 2. Assess treatment, perform counseling
4	6 weeks after visit 3	1. Review treatment plan until goal is reached 2. Perform anthropometric measurements every 3 months after enrollment
5 & subsequent visits	• Every 3 months for patients with Mild Hypertension (treated by CVD nurse) • Every 2 months for patient with Moderate Hypertension (treated by CVD nurse) • Monthly for Patients with High (treated by Physicians only)	1. Re-check BP, review treatment, assess for risk factors, perform Hypertension counseling 2. Conduct follow up assessment every 6 months after enrollment

Supplementary Figure 2. guidelines for patient visits

Phase	Activity	Community Health Officer	Licensed Chemical Seller	CVD Nurse	Physician
Phase 1: Screening	Community BP screening	Yes	Yes	No	No
	Screening referral	Yes	Yes	No	No
Phase 2: Diagnostic Evaluation	Confirmation of BP (HTN) diagnosis	No	No	Yes	Yes
	Staging of degree of HTN	No	No	Yes	Yes
	Assessment of other CVD risk factors	No	No	Yes	Yes
	Assessment of prevailing CVD symptoms	No	No	Yes	Yes
	Overall risk assessment/ Stratification	No	No	Yes	Yes
	Assessment of family history of CVD	No	No	Yes	Yes
	Laboratory investigation	No	No	Yes	Yes
	Assessment of target organ complication	No	No	Yes	Yes
	Assessment of Lifestyle Issues	No	No	Yes	Yes
	Diagnostic referral	No	No	Yes	No
	Baseline Anthropometry	No	No	Yes	Yes
Phase 3: Management, Monitoring & Follow Up	Recommendation for drug treatment	No	No	Yes	Yes
	Medication Dispensing	No	Yes	No	No
	Recommendation for Non-drug treatment	Yes	Yes	Yes	Yes
	Evaluation of drug side effects	No	Yes	Yes	Yes
	Monitoring of BP response to treatment	No	Yes	Yes	Yes
	Adherence Counselling	No	Yes	Yes	Yes
	Anthropometric monitoring	No	No	Yes	Yes
	Regular follow up and interaction	No	No	Yes	No
	Management referral	No	No	Yes	Yes*

Supplementary Table 1) Summary of roles of various service delivery personnel
*In rare instances, certain patients may be referred by the Physician to a hypertension specialist

I. Diuretic: Bendroflumethiazide. –initial dose, 2.5mg daily. Maximum dose of 5mg daily.

II. Beta-blocker: Atenolol-initial dose of 50mg daily. Maximum dose of 100mg daily provided the heart rate is greater than 60/min on the lower dose.

III. Calcium channel blocker: Nifedipine retarde or XL -initial dose 30mg daily. Maximum dose of 60 to 90 mg daily.

Supplementary Table 2) Recommended medications and dosages

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	3-4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	5-6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	6-7
Study size	10	Explain how the study size was arrived at	6-7

Continued on next page

Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	7
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	7
		(*b*) Describe any methods used to examine subgroups and interactions	7
		(*c*) Explain how missing data were addressed	7
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	7
		(*e*) Describe any sensitivity analyses	
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	7-8
		(b) Give reasons for non-participation at each stage	7-8
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	7-9
		(b) Indicate number of participants with missing data for each variable of interest	7-9
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	7-9
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	10-13
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	8-14
		(*b*) Report category boundaries when continuous variables were categorized	
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	

Continued on next page

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	10-14
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	16
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	17

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.