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India Hypertension Control Initiative—Hypertension treatment and blood pressure control in a cohort in 24 sentinel site clinics

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Abstract

The India Hypertension Control Initiative (IHCI) is a multi-partner initiative, implementing and scaling up a public health hypertension control program across India. A cohort of 21,895 adult hypertension patients in 24 IHCI sentinel site facilities in

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four Indian states (Punjab, Madhya Pradesh, Maharashtra, and Telangana), registered from January 2018 until June 2019 were assessed at baseline and then followed up for blood pressure (BP) control and antihypertensive medication use. Among all registrations, 11 274 (51%) of the patients returned for a follow-up visit between July 2019 and September 2019. Among patients returning for follow-up, 26.3% had BP controlled at registration, and 59.8% had BP controlled at follow-up ($p < .001$). The absolute improvement in BP control was more than two times greater in primary care (48.1 percentage point increase) than secondary care facilities (22.9 percentage point increase). Most IHCI patients received prescriptions according to state-specific treatment protocols. This study demonstrates that a scalable public health hypertension control program can yield substantial BP control improvements, especially in primary care settings. However, high loss to follow-up limits population health impact; future efforts should focus on improving systems to increase the likelihood that patients will return to the clinic for routine hypertension care.

1 | INTRODUCTION

Hypertension is a major risk factor for cardiovascular disease globally and a leading cause of premature death and disability. Globally, one third (31.1%) of the adults had hypertension in 2010, and only 13.8% had blood pressure under control.[1] In a nationally representative survey of adults above 18 years in India in 2012-14, nearly one in four had hypertension.[2] Only 8% of adults in the 15-49 years age group with hypertension had blood pressure under control.[3]

The Government of India (GOI) has adopted a national action plan to prevent and control noncommunicable diseases (NCDs) aligned with the WHO's global targets to be achieved by 2025. These include a 25% relative reduction in overall mortality from cardiovascular diseases and a 25% relative reduction in raised blood pressure prevalence.[4] To address the threat of hypertension and other NCD conditions to population health, the Government of India initiated a National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) in 2010-11.[5] NPCDCS initiated a population-based program to screen and manage for hypertension, diabetes, and cancers of the breast, cervix, and oral cavity.[6]

The India Hypertension Control Initiative (IHCI), a multi-partner initiative, aims to strengthen the Government of India's program by strengthening the management of diagnosed hypertension in primary health care settings. It adapts the World Health Organisation (WHO) HEARTS technical package strategies to improve India's hypertension management and control.[7] IHCI partners included the Government of India Ministry of Health & Family Welfare, Indian Council of Medical Research (ICMR), State Governments, and WHO India. Resolve to Save Lives, an initiative of Vital Strategies is a technical partner. IHCI Phase 1 was initiated in November 2017 and is currently active in all the public health facilities in 40 districts of Punjab, Kerala, Madhya Pradesh, Telangana, and Maharashtra. We identified six sentinel site health facilities in each of the four states for in-depth data collection. To scale the interventions and gradually integrate into the national program, Phase 2 of the project was launched in July 2019 and will cover 100 districts across all Indian States, including a population of approximately 200 million people.

Sentinel sites collected detailed real-time data under programmatic conditions documenting the effectiveness of IHCI interventions. This report describes the change in blood pressure control from baseline to follow-up in a cohort of hypertensive patients who initiated treatment in the IHCI sentinel health facilities. We also describe antihypertensive medication prescription practices.

2 | METHODS

2.1 | Study design and population

A cohort study was completed in 24 purposively selected public sector facilities identified as sentinel sites in four Indian states: Punjab, Madhya Pradesh, Maharashtra, and Telangana. We selected the sites in consultation with the states ensuring representation of all types of health facilities. Of the 24 sites, eight were secondary care facilities located in urban areas, including district and sub-district hospitals. They not only serve as secondary care facilities for the district but also provide primary care such as outpatient clinics for patients with hypertension. Of the remaining 16 facilities, eight were primary health care centers (PHC), and eight others were larger community health centers (CHC). We included all patients above 18 years of age registered under the IHCI program in the selected public sector facilities from January 2018 to June 2019, with follow-up analyzed until September 2019.

The cohort included patients already on treatment as well as patients with hypertension who were newly detected during population-based screening or opportunistic screening at the health facilities.

2.2 | Intervention strategy

The IHCI has five intervention strategies based on the HEARTS technical package. First, a simple, standard drug- and dose-specific treatment protocol including three standard classes of antihypertensive drugs [calcium channel blocker (CCB), angiotensin II receptor blocker (ARB), and a thiazide or thiazide-like diuretic] (Supplementary Appendix 1a and 1b- Protocols); second, uninterrupted adequate availability and distribution of protocol drugs in all facilities. Third, community-based treatment and decentralization of care to lower-level facilities to enable blood pressure measurement and drug refills closer to the patient's home. Fourth, patient-centered care approaches such as minimum 30-day drug prescription, counseling, and documentation of visits in a treatment card or an Android phone-based application, Simple app, available to program staff in two states for easy retrieval of records. Fifth, monitoring systems track individual patient and treatment cohort progress with medication lists and standard indicators such as quarterly blood pressure control. Monitoring systems include paper-based patient hypertension cards in Madhya Pradesh and Telangana and the mobile phone-based, digital Simple app in Punjab and Maharashtra.

2.3 | Patient registration and follow-up

Patients were registered as per the IHCI protocol. In each facility, NCD nurse issued a blood pressure (BP) passport card to the patient that included a unique QR code and number. Patients carried their blood pressure passport cards every time they visited any of the public sector facilities for a follow-up visit to continue the treatment under the same registration and continuous monitoring.

The patient visited the nurse at regular appointments, during which time blood pressure was measured. On a patient's day of visit to the health facility, the nurse measured and entered the blood pressure reading in the paper-based treatment card or into a digital system using Simple App. Simple is a user-friendly android App requiring minimal time to document patient's blood pressure and medications to help monitor blood pressure control.[8]

Nurses measured the blood pressure for all patients in the sitting position using one of the professional digital BP monitors provided by the project (A&D UM-211 or Omron HEM-1300 BP monitors). A detailed checklist was displayed in all the clinics for easy understanding of the nurses (Supplementary appendix 2 - BP measurement Checklist).

Subsequently, patients went to the medical officer who initiated, maintained, or intensified the prescription antihypertensive medication regimen, following which medications were dispensed for at least 30 days on-site at the health facility. All the public sector health facilities included in the project provided medications free of cost. State governments have procurement agencies which do the bulk purchase of medications and distribute to the health facilities periodically.

Patients were advised to continue the treatment at the place where they were registered unless the patient wanted to take treatment elsewhere. Cross referrals from secondary to primary care facilities were not routinely done.

2.4 | Operational definitions

Hypertension diagnosis was defined as a blood pressure of ≥140 mmHg or ≥90 mmHg on at least two occasions on different days, or prior treatment with antihypertensive medications at the time of registration irrespective of their BP reading, or ≥160 mmHg or ≥100 mmHg on a single day with two readings.[9] BP was considered under control if systolic BP is <140 mmHg and diastolic BP is <90 mmHg during the most recent visit, which is the target as per India's national program NPCDCS.[10] If patients registered under IHCI and followed up until the previous quarter did not return for a follow-up visit consecutively for three months in the next quarter or more, this was considered a missed visit.

2.5 | Data collection

We recruited a research staff nurse in each of the sentinel sites. Nurses were trained in data collection and provided with an android tablet with an open data kit tool for data collection. We collected data on sociodemographic characteristics, comorbidity at the time of registration (baseline), BP readings (systolic and diastolic), and antihypertensive drugs prescribed at baseline and follow-up visits. The nurses contacted the patients once in a quarter by phone if they did not return for a visit. The data was synced from the digital open data kit to a central computer server daily.

2.6 | Data analysis

Epi Info software version 7.2.4.0 was used for data analysis. We described IHCI sentinel site hypertensive patient characteristics according to age group, facility type, history of comorbidities, previous history of hypertension, and grades of hypertension at baseline for individuals registered between January 2018 and June 2019. We computed proportions of patients who missed their follow-up visit during July-September, 2019. Among patients who returned for at least one follow-up visit during July-September, 2019, we calculated the proportion with controlled BP and used McNemar's chi-square to test for statistical significance between the proportion of hypertensive patients with blood pressure control at the time of registration and the proportion at the time of follow-up. We also estimated the mean SBP and DBP at baseline & follow-up and used a paired t test to compare for significant differences.

2.7 | Human subjects protection

We obtained written informed consent from all patients registered for hypertension treatment in the sentinel sites. We also obtained approval for these research activities from the institutional ethics committee of the ICMR-National Institute of Epidemiology, Chennai.

3 | RESULTS

A total of 21 895 people with hypertension were registered in 24 IHCI sentinel sites in four different Indian states (Punjab, Madhya Pradesh, Maharashtra, and Telangana) between January 2018 and June 2019. Madhya Pradesh had 7320 registrations (33% of the total), which was the highest, and Telangana had the lowest with 2361 (11%; Table 1). The Median follow-up duration was 163 days (IQR 106-251 days). Overall, 12 050 registrations (55%) occurred in hospitals, and 9845 (45%) were at the primary care level (PHC or CHC). Across all four states, 62% of the patients were previously diagnosed with hypertension at the time of registration. Majority were taking drugs however we could not verify if they were taking drugs regularly. The great majority of patients (91%) had been previously diagnosed with hypertension in Telangana and Maharashtra. On the other hand, Punjab had only 30% previously diagnosed patients. Among the registered patients (n = 21,895), 60% were in the 50-69 years age group, and less than 1% were under the age group of 30 years. Females comprised 58% of the registered patient population. Among all patients, 14% reported having diabetes at the time of registration (the proportion ranged from 8% in Punjab to 25% in Maharashtra).

Overall, 64% of the patients had uncontrolled grade I hypertension (SBP 140-159 and/or DBP 90-99), 12.4% had uncontrolled grade II hypertension (SBP 160-179 and/or DBP 100-109), and 3.2% had uncontrolled grade III hypertension (SBP ≥180 or DBP ≥110), at the time of registration (Table 2). Among patients with a new diagnosis of hypertension, nearly 79.5% had grade I hypertension. The proportion of people with blood pressure above 159 mmHg or above 99 mmHg was much higher (24.7%) in Maharashtra than in Telangana (11.8%). Among people who were already on treatment, 32.7% had controlled BP at the time of registration; nearly half (54.7%) had grade I hypertension, and 12.6% had grade II or III hypertension.

Among all patients registered until June 2019, 11 274 (51%) returned for a follow-up visit between July 2019 and September 2019 (Table 3). Nearly half of the patients above 50 years came for a follow-up visit compared to only 28% below 30 years of age. Patients who did not return for follow-up visits might have taken treatment elsewhere; however, this information was not collected. The proportion of total registered patients who returned for a scheduled follow-up visit was highest in Telangana (72.6%) and lowest in Punjab (27.6%). Among patients who came for follow-up in July 2019-Sept2019, only 26.3% of registered hypertension patients had BP controlled at registration, and 59.8% had BP controlled at follow-up (McNemar's chi-square <0.001). Blood pressure control improved significantly across all age groups, types of facilities, and states. BP control among patients returning for follow-up was highest in Telangana (78.3%) and lowest in Punjab (54.7%). The absolute improvement in BP control was highest in Punjab (43.4 percentage point increase) and lowest in Maharashtra (21.9 percentage point increase). The absolute difference in percent BP control from baseline to follow-up was 53.6% among people <30 years of age and 31.5% among people ≥70 years of age. Achieved BP control on follow-up at the primary care facilities was 70.4% compared to 52.2% in the secondary care facilities. The absolute increase in BP control was more than twice as high in primary care (48.1%) than secondary care facilities (22.9%).

Baseline mean systolic blood pressure (SBP) was highest in Punjab (159.3 mmHg) and lowest in Telangana (139.1 mmHg) at

TABLE 1 Descriptive characteristics of the patients with hypertension and the comorbidities in 24 clinics, India

		Punjab (N = 6321)	Madhya Pradesh (N = 7320)	Maharashtra (N = 5893)	Telangana (N = 2361)	Overall (21 895)
Characteristics		**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Age groups (Years)	<30	39 (0.6)	43 (0.6)	7 (0.1)	10 (0.4)	99 (0.5)
	30-49	1484 (23.5)	1471 (20.1)	848 (14.4)	434 (18.4)	4237 (19.4)
	50-69	3595 (56.9)	4461 (60.9)	3649 (61.9)	1493 (63.2)	13 198 (60.3)
	≥70	1203 (19.0)	1345 (18.4)	1389 (23.6)	424 (18.0)	4361 (19.9)
Sex	Male	2443 (38.6)	3178 (43.4)	2451 (41.6)	1158 (49.0)	9230 (42.2)
	Female	3878 (61.4)	4142 (56.6)	3442 (58.4)	1203 (51.0)	12 665 (57.8)
Types of facilities	Hospitals (District and sub-district)	3103 (49.1)	4253 (56.6)	3432 (58.2)	1262 (53.5)	12 050 (55.0)
	Primary health care centers (community health centers and primary health centers)	3218 (50.9)	3067 (41.9)	2461 (41.8)	1099 (46.5)	9845 (45.0)
Comorbidities	Past H/o Heart attack	30 (0.5)	136 (1.9)	75 (1.3)	42 (1.8)	283 (1.3)
	Past H/o Stroke	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
	Past H/o Kidney disease	11 (0.2)	4 (0.1)	11 (0.2)	24 (1.0)	50 (0.2)
	Past H/o Diabetes	505 (8.0)	687 (9.4)	1449 (24.6)	442 (18.7)	3083 (14.1)
	Past H/o Hypertension	1930 (30.5)	4092 (55.9)	5387 (91.4)	2166 (91.7)	13 575 (62.0)

TABLE 2 Grades of Hypertension at the time of registration in 24 clinics, India

Hypertension grades among all registered patients (mmHg)	Punjab n (%)	Madhya Pradesh n (%)	Maharashtra n (%)	Telangana n (%)	Overall n (%)
SBP < 140 and DBP < 90	521 (8.2)	1084 (14.8)	1974 (33.5)	861 (36.5)	4440 (20.3)
Grade I (SBP 140-159 or DBP 90-99)	4470 (70.7)	4906 (67.0)	3281 (55.7)	1385 (58.7)	14 042 (64.1)
Grade II (SBP 160-179 or DBP 100-109)	1024 (16.2)	1063 (14.5)	521 (8.8)	107 (4.5)	2715 (12.4)
Grade III (SBP >= 180 or DBP >= 110)	306 (4.8)	267 (3.6)	117 (2.0)	8 (0.3)	698 (3.2)
Overall (N)	6321	7320	5893	2361	21 895
Hypertension grades among newly detected patients (mmHg)					
Grade I (SBP 140-159 or DBP 90-99)	3488 (79.4)	2572 (79.7)	381 (75.3)	172 (88.2)	6613 (79.5)
Grade II (SBP 160-179 or DBP 100-109)	701 (16.0)	523 (16.2)	98 (19.4)	23 (11.8)	1345 (16.2)
Grade III (SBP >= 180 or DBP >= 110)	202 (4.7)	133 (4.1)	27 (5.3)	0 (0.0)	362 (4.4)
Overall (N)	4391	3228	506	195	8320
Hypertension grades among already treated patients (mmHg)					
SBP < 140 and DBP < 90	521 (27.0)	1084 (26.5)	1974 (36.6)	861 (39.8)	4440 (32.7)
Grade I (SBP 140-159 or DBP 90-99)	982 (50.8)	2334 (57.0)	2900 (53.8)	1213 (56.0)	7429 (54.7)
Grade II (SBP 160-179 or DBP 100-109)	323 (16.7)	540 (13.2)	423 (7.9)	84 (3.9)	1370 (10.1)
Grade III (SBP >= 180 or DBP >= 110)	104 (5.4)	134 (3.3)	90 (1.7)	8 (0.4)	336 (2.5)
Overall (N)	1930	4092	5387	2166	13 575

baseline. Mean SBP decline ranged between 10.7-11.7 mmHg, and the mean DBP decline ranged between 6.7-7.3 mmHg in various age groups except below 30 years. Overall, mean SBP declined by 11 mmHg and DBP by 6.9 mmHg (p-value < .001). Mean SBP decline over time was highest in Punjab (18.0 mmHg) and lowest in Maharashtra (7.2 mmHg) (Table 4).

All four states had a CCB (amlodipine), ARB (telmisartan or losartan), and a diuretic (chlorthalidone or hydrochlorothiazide) in the state protocol. The Maharashtra protocol included telmisartan 40 mg at the second step of the treatment protocol after amlodipine 5 mg; all the rest included telmisartan at the third step after amlodipine was doubled from 5 mg to 10 mg (Supplementary appendix 1a and 1b—Treatment protocols). Among 11 274 patients who had at least one visit during July-September, 2019, physicians prescribed only one drug (monotherapy) for 63.6% of the patients (Table 5). Overall, most commonly prescribed drugs/combinations were amlodipine 5 mg (44.6%), amlodipine 5mg + Telmisartan 40 mg (12.2%), amlodipine 10 mg (8.3%), enalapril (3.4%), and telmisartan 40 mg (5.3%). Amlodipine 5 mg was the most prescribed drug across all states. The second most prescribed drug was Amlodipine 10 mg in Telangana (15%) and Madhya Pradesh (13.4%). The second common prescription was Amlodipine 5 mg + Telmisartan 40 mg in Punjab (23.7%) and Maharashtra (11.6%). Nearly one quarter (23.6%) of the patients were on two drugs (dual therapy). Among the people on dual therapy across all states, the most common combination (15.7%) was amlodipine (5 or 10 mg) plus telmisartan 40 mg. Nearly 154 (1.4%) patients were on Atenolol (25 or 50 mg), mostly from Telangana. Only 0.6% of patients were on three drugs, and 12.3% were on various combinations of two or three other drugs. Across states, prescription practices varied. Maharashtra had very few amlodipine 10 mg prescriptions (consistent with their protocol design). Punjab had nearly one-fourth of the patients on the combination of amlodipine 5 mg and telmisartan 40 mg (per protocol) and 10.4% on telmisartan 40mg + chlorthalidone 12.5mg (off-protocol). Diuretics, the third-line drug in the protocol, were used in combination with other drugs in only 2.3% of patients: 13% of patients in Punjab, less than 1% of patients in Maharashtra and Madhya Pradesh, and none of the patients in Telangana (Table 5).

4 | DISCUSSION

We measured the efficacy of a scalable, multi-component public health hypertension control program in a cohort of more than 21 000 patients in the IHCI sentinel sites in four Indian states. Implementing a comprehensive hypertension control intervention package based on the WHO HEARTS technical package[7] is feasible across primary and secondary public sector facilities in India and leads to substantial improvement in hypertension control. Our study documented significant BP control improvement after an average of six months follow-up across all the health facilities and irrespective of age, sex, type of facility, or state. A remarkable finding was the greater absolute improvement in BP control in primary health care facilities than secondary care facilities. However, half of the patients did not return for a scheduled care visit during the study follow-up period. There were wide variations across states highlighting the need for state-specific interventions, emphasizing community awareness, and designing models of care that bring treatment closer to their homes.

TABLE 3 Blood pressure control at follow-up during July-Sept, 2019 as compared to baseline in 24 clinics, India

	Registrations between January, 2018 and June, 2019 (N = 21 895)	People who had FU visit between July and September, 2019 (N = 11 274)	Hypertension control at the time of registration (N = 11 274)	Hypertension control at the time of latest FU visit (N = 11 274)	McNemars-chi-square test (P-value)
Categories	**n (%)**	**n (%)**	**n (%)**	**n (%)**	
State					
Punjab	6321 (28.9)	1746 (27.6)	198 (11.3)	955 (54.7)	<0.001
Madhya Pradesh	7320 (33.4)	3658 (50.0)	685 (18.7)	2099 (57.4)	<0.001
Maharashtra	5893 (26.9)	4155 (70.5)	1445 (34.8)	2349 (56.5)	<0.001
Telangana	2361 (10.8)	1715 (72.6)	641 (37.4)	1342 (78.3)	<0.001
Sex					
Male	9230 (42.2)	4739 (51.3)	1139 (24.0)	2625 (55.4)	<0.001
Female	12 665 (57.8)	6535 (51.6)	1830 (28.0)	4120 (63.0)	<0.001
Age groups (years)					
<30	99 (0.5)	28 (28.3)	6 (21.4)	21 (75.0)	<0.001
30-49	4237 (19.4)	1896 (44.7)	506 (26.7)	1205 (63.6)	<0.001
50-69	13 198 (60.3)	7059 (53.5)	1912 (27.1)	4251 (60.2)	<0.001
≥70	4361 (19.9)	2291 (52.5)	545 (23.8)	1268 (55.3)	<0.001
Facility Level					
Hospitals (District and sub-district)	12 050 (55.0)	6521 (50.4)	1910 (29.3)	3401 (52.2)	<0.001
Primary health care centers (community health centers and primary health centers)	9845 (45.0)	4753 (48.3)	1059 (22.3)	3344 (70.4)	<0.001
Overall	21 895	11 274 (51)	2969 (26.3)	6745 (59.8)	<0.001

TABLE 4 Mean systolic blood pressure (SBP) and diastolic blood pressure (DBP) at registration and follow-up during July-September, 2019 in 24 clinics, India

	People who had FU visit between July and September, 2019 (N = 11 274)	Mean SBP in mmHg (SD) at baseline	Mean SBP in mmHg (SD) at recent follow-up	Mean difference of SBP (mmHg) (95% CI)	Paired t test for SBP (p-value)	Mean DBP in mmHg (SD) at baseline	Mean DBP in mmHg (SD) at recent follow-up	Mean difference of DBP (mmHg) (95% CI)	Paired t test for DBP (p-value)
State									
Punjab	1746	159.3 (21.7)	141.3 (19.9)	18.0 (16.9 - 19.2)	0.000	91.6 (12.4)	82.0 (11.0)	9.6 (9.0 - 10.3)	<0.001
Madhya Pradesh	3658	151.1 (20.2)	138.3 (19.7)	12.8 (12.0 - 13.6)	0.000	86.7 (13.2)	79.0 (12.9)	7.7 (7.2 - 8.1)	<0.001
Maharashtra	4155	144.2 (21.5)	137.0 (19.7)	7.2 (6.5 - 7.9)	0.000	82.1 (12.6)	77.0 (12.1)	5.1 (4.7 - 5.6)	<0.001
Telangana	1715	139.1 (18.7)	130.0 (16.0)	9.1 (8.1 - 10.1)	0.000	84.5 (11.5)	78.1 (10.5)	6.5 (5.9 - 7.1)	<0.001
Sex									
Male	4739	149.3 (21.6)	139.0 (19.7)	10.3 (9.6 - 11.0)	0.000	86.8 (13.1)	80.2 (12.0)	6.6 (6.2 - 7.0)	<0.001
Female	6535	147.1 (21.6)	135.6 (19.2)	11.5 (11.0 - 12.0)	0.000	84.4 (12.9)	77.4 (12.0)	7.0 (7.0 - 7.4)	<0.001
Age groups (years)									
<30	28	146.6 (22.4)	129.7 (12.7)	17.0 (7.4 - 26.5)	0.001	89.9 (14.4)	77.3 (10.0)	13.0 (6.3 - 19.0)	<0.001
30-49	1896	146.4 (21.1)	134.7 (17.8)	11.7 (10.7 - 12.7)	0.000	88.7 (13.3)	81.4 (11.5)	7.3 (6.7 - 8.0)	<0.001
50-69	7059	147.5 (21.4)	136.7 (19.5)	10.7 (10.2 - 11.3)	0.000	85.1 (12.8)	78.4 (12.0)	6.7 (6.4 - 7.1)	<0.001
≥70	2291	150.9 (22.7)	139.8 (20.6)	11.1 (10.1 - 12.1)	0.000	83.6 (13.0)	76.8 (12.4)	6.8 (6.2 - 7.4)	<0.001
Overall	11 274	148.0 (21.7)	137.0 (20.0)	11.0 (10.6 - 11.4)	0.000	85.4 (13.0)	78.6 (12.1)	6.9 (6.6 - 7.1)	<0.001

TABLE 5 Prescription practices for hypertension treatment in 24 clinics, India

	Punjab	Madhya Pradesh	Maharashtra	Telangana	Grand total
Name of drugs	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Amlodipine 5 mg	559 (32.0)	1624 (44.4)	2019 (48.6)	822 (47.9)	5024 (44.6)
Amlodipine 10mg	186 (10.7)	492 (13.4)	2 (0.0)	258 (15.0)	938 (8.3)
Telmisartan 40 mg	113 (6.5)	258 (7.1)	109 (2.6)	118 (6.9)	598 (5.3)
Telmisartan 80mg	0 (0.0)	11 (0.3)	1 (0.0)	11 (0.6)	23 (0.2)
Losartan 25mg	33 (1.9)	8 (0.2)	0 (0.0)	0 (0.0)	41 (0.4)
Atenolol 25mg	0 (0.0)	1 (0.0)	15 (0.4)	3 (0.2)	19 (0.2)
Atenolol 50mg	7 (0.4)	2 (0.1)	18 (0.4)	108 (6.3)	135 (1.2)
Enalapril 5 mg	0 (0.0)	2 (0.1)	383 (9.2)	0 (0.0)	385 (3.4)
Amlodipine 5mg + Telmisartan 40mg	413 (23.7)	385 (10.5)	481 (11.6)	92 (5.4)	1371 (12.2)
Amlodipine 5mg + Telmisartan 80mg	4 (0.2)	1 (0.0)	58 (1.4)	4 (0.2)	67 (0.6)
Amlodipine 10mg + Telmisartan 40mg	78 (4.5)	243 (6.6)	1 (0.0)	67 (3.9)	389 (3.5)
Amlodipine 10mg + Telmisartan 80mg	5 (0.3)	37 (1.0)	19 (0.5)	32 (1.9)	93 (0.8)
Amlodipine 5mg + Losartan 25mg	34 (1.9)	11 (0.3)	0 (0.0)	0 (0.0)	45 (0.4)
Telmisartan 40mg + Chlorthalidone 12.5mg	181 (10.4)	2 (0.1)	8 (0.2)	0 (0.0)	191 (1.7)
Amlodipine 5mg + other drug	3 (0.2)	92 (2.5)	389 (9.4)	10 (0.6)	494 (4.4)
Amlodipine 5mg + Telmisartan 40mg + Chlorthalidone 12.5 mg	29 (1.7)	0 (0.0)	5 (0.1)	0 (0.0)	34 (0.3)
Amlodipine 10mg + Telmisartan 40mg + Chlorthalidone 12.5 mg	15 (0.9)	6 (0.2)	0 (0.0)	0 (0.0)	21 (0.2)
Amlodipine 10mg + Telmisartan 40mg + Chlorthalidone 25 mg	0 (0.0)	14 (0.4)	0 (0.0)	0 (0.0)	14 (0.1)
Others	86 (4.9)	469 (12.8)	647 (15.6)	190 (11.1)	1392 (12.3)
Total	1746	3658	4155	1715	11 274

Patients who did not return for follow-up visit might have taken treatment elsewhere, so absolute control rates might have been different than reported here. The major hospitals in all the states were more crowded, had more patients with co-morbid conditions, and lacked sufficient staffing, any or all of which could have led to suboptimal monitoring of BP and titration of medications in response to uncontrolled BP. Our results suggest that hypertension may be better managed in primary health care settings, which are closer to patients' homes. In an intervention program in Cuba, the proportion of patients with BP control increased from 59% to 68% among 2000 + patients after implementing WHO HEARTS strategies.[11] Effectiveness of primary care interventions in improving blood pressure control has been documented in various settings.[12] Change in the BP control was less in the older age group than the younger age group. Physicians should be counseled to progressively and steadily but safely titrate the dose and the drugs to achieve BP control in the older age groups.

Nearly half of the patients registered in the IHCI sentinel sites did not return for a scheduled follow-up visit. We need in-depth studies to understand the other reasons for loss to follow-up, to increase patient retention. The proportion of patients who followed up varied among the states. The highest proportion followed up in Maharashtra and Telangana and lowest in Punjab. This variation may be explained by differential operationalization of community-level interventions across states and drug shortages in Punjab in initial stages. Maharashtra and Telangana involved field-level health workers who may have motivated the patients to come for regular follow-up. These potential drivers of lower follow-up need to be investigated by contacting and interviewing people who did not return for follow-up across various states. Studies from India and Thailand reported improved awareness or control involving lay health workers and community volunteers to improve hypertension management.[13,14] In a community-based intervention in southern state Kerala, community volunteers' monitoring of blood pressure and education increased blood pressure control from 6.5% to 21.7%.[13] The IHCI will explore the effectiveness of community-based interventions to improve outcomes. Further evaluation is needed in different states and urban and rural areas to determine optimal means to improve blood pressure control.

Most prescriptions were issued according to state-approved protocols. The training programs for doctors and the design of protocols in consultation with various stakeholders facilitated the acceptance of protocols. Our protocol implementation experience was consistent with a study from Cuba, which showed that

an algorithm-based approach and capacity building of doctors improved prescriber compliance to the use of protocol drugs.[11] In another study from Xinjiang, China, training 313 primary care practitioners with standard treatment protocol increased health care provider compliance to protocol and improved BP control from 10% to 15%.[15] In our setting, the protocols included CCBs, ARBs, and diuretics, with CCB as the first line because laboratory investigations are not required before initiating the drug and are not always available in all centers. The preference for CCB, ARB, and diuretics for hypertension management was also reported in another study among multiple private sector clinicians in India.[16] A small proportion of patients were on beta-blockers, which were not included in the state-prescribed protocols. However, most of them started treatment before the introduction of protocols.

Most patients received monotherapy, and a small proportion received dual therapy. Patients were elevated blood pressure often did not receive additional or higher-dose medications as indicated by protocol. This phenomenon, often described as therapeutic inertia, has been well documented in many countries. A study of 4725 hypertensives with uncontrolled blood pressure from private sector clinics in various Indian states reported single-drug therapy among 45.4% of the patients, although many of these patients' blood pressure remained elevated.[16] Further training of the doctors and innovative methods are needed to remind the physician to escalate treatment when the patient continues to have high BP. An intervention consisting of physician education and feedback on hypertension control rates improved the BP control in the intervention counties compared to the control group in Sweden.[17] We also need to document the patients' challenges in taking medications regularly and barriers in accessing health facilities or getting drug refills.

A limitation of this study was that we could not collect reliable information on adherence to lifestyle modification, which might have influenced the BP control. We also could not collect laboratory parameters such as serum creatinine and electrolytes. Moreover, as noted above, some patients may have continued treatment at facilities other than those we monitored, so that actual control rates may be higher than those we documented.

State health leaders and other stakeholders recognized the effectiveness of IHCI strategies, and several states have further expanded treatment programs in addition to the national commitment to Phase 2 expansion. In 2020, we expanded the IHCI to additional districts within five states and all other Indian states. We recommend scalable national hypertension control programs that include simple, easy-to-follow drug- and dose-specific treatment protocols, availability of good quality protocol drugs, decentralization of care to improve patient retention and hypertension control, standard information systems which capture BP control, and a minimum of 30 days' medication supply for patients. Continuous training and supportive supervision of doctors is required to disseminate best clinical practices and overcome therapeutic inertia. We aim to reduce loss to follow-up and missed visits by counseling for adherence at every visit, implementing phone call-based reminders from nurses, and adding visits to patients' homes by field-level health workers.

In conclusion, we demonstrated substantial BP control improvements in a cohort of hypertension patients at sentinel sites within four Indian states implementing the IHCI following the WHO HEARTS technical package adapted to the Indian context. BP control improved more in the primary care facilities compared to secondary care facilities. Most patients received prescriptions according to state-specific treatment protocols. However, nearly half of the patients did not return for a follow-up visit, limiting the population health impact of the program, and will be the focus of program improvement efforts.

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CONFLICT OF INTEREST

None.

AUTHOR CONTRIBUTION

Each of the listed authors (PK, AK, MS, JM, CD, LS, TC, SB, VV, RD, SP, ST, GBS, SB, KD, BD, SD, RB, CJ, VB, SK, SC, SR, CS, GP, SK, VV, PU, PG, SY, RSD, SR, FT, BB) meet the criteria for "Authorship" in accordance with the ICMJE recommendations as below: (1) Substantial contributions to the conception or design of the work; (2) Drafting the work or revising it critically for important intellectual content; (3) Final approval of the version to be published; (4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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