# openheart Incident hypertension in urban slums of central India: a prospective cohort study

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## **ABSTRACT**

**Background** Numerous studies have highlighted the burden of hypertension by estimating its prevalence. However, information regarding quantum and characteristics of persons whose blood pressure converts to hypertension range from their previous state of prehypertension or normal blood pressure is crucial for any public health programme. We aimed to estimate incidence rate of hypertension and to identify risk factors for the same, so that it is useful for programme implementation.

Methods We established a cohort of adults residing in urban slums of Bhopal, who were registered in a baseline cardiovascular risk assessment survey, which was performed between November 2017 and March 2018. Blood pressure assessment was done at least three times at baseline for diagnosis of hypertension, which was defined as systolic blood pressure ≥140 mm Hg or diastolic blood pressure ≥90 mm Hg on two occasions. Participants who did not have a diagnosis of hypertension were followed up during April-June 2019.

Results Of the 5673 participants assessed at baseline, 4185 did not have hypertension of which 3199 (76.4%) were followed up after a median on 1.25 years (IQR 1.08-1.60) and a total of 170 (5.31%) individuals were detected with incident hypertension. Overall incidence rate of hypertension was 4.1 (95% CI 3.54 to 4.75) per 100 person-years of follow-up. On multivariate analysis, age (relative risk/RR 1.98; 95% CI 1.19 to 3.3, for age >60 years), being in first and second wealth tertile (T-1 RR 1.85; 95% Cl 1.17 to 2.91) and being illiterate (RR 1.94; 95% Cl 1.31 to 2.86) were significant predictors of incident hypertension, Individuals who had prehypertension at baseline also had a significantly increased risk of developing hypertension (RR 2.72; 95% CI 1.83 to 4.03).

**Conclusions** We found that incidence of hypertension in urban slums of central India is higher with increasing age and in men. Illiteracy, lower Wealth Index and prehypertension are other determinants. We also demonstrate feasibility of establishing a cohort within the public health delivery system, driven by efforts of community health workers.

# INTRODUCTION

Hypertension is a leading cause of cardiovascular diseases (CVDs) globally and in India. About one-third of all urban and one-fourth of all rural adults in India have hypertension.

# **Key questions**

# What is already known about this subject?

▶ While prevalence of hypertension in adults is high and is increasing over time, estimates about incidence of hypertension from low/middle-income countries are limited. Previous estimates from India have ranged from 3.3% to 8.2%.

# What does this study add?

► This study provides estimates of incidence of hypertension and also identifies vulnerable groups within the urban slum population, who are more at risk.

# How might this impact on clinical practice?

- ► Hypertension, being a lifelong condition, is not likely to change its prevalence in short term. Reduction in annual incidence can be an achievable aim and will help programme managers to evaluate benefit.
- ► Robust incidence rates will improve planning for scale up of hypertension control services in the community.

Previous studies by our group have estimated prevalence of hypertension and its risk factors in state-wide representative survey of Madhya Pradesh. We found that prevalence to be 25.7% in urban and 20.8% in rural areas.<sup>2</sup> These numbers translate into more than 200 million individuals with hypertension in India.<sup>3</sup> Given this huge burden, National Program for Cancer, Diabetes, Cardiovascular diseases and Stroke (NPCDCS) launched by the government of India envisages annual screening for hypertension in all adults above 30 years of age. 4 Once such screening is fully operationalised, individuals with newly detected hypertension are likely to add on to the overall burden. There are only a limited studies on incidence of hypertension from India. In a previous cohort of 300 individuals (age range 15-64 years) from southern Indian state of Kerala, India, nearly one-fourth individuals developed hypertension in 7 years of follow-up from 2003 to 2010.5 This 3.3% annual incidence was the only community-based benchmark from India, until publication of a multicity CARRS



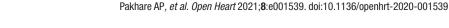
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Study (Chennai, New Delhi and Karachi) in 2017 among adults with age 20 years or more, provided an annual incidence estimate of 8.2%. A recently published cohort from eastern state of West Bengal has reported incidence of hypertension among adults of age 18 years or more to be 5.9% for women and 7.9% for men, respectively.

Rise in incidence has led to increase in prevalence of hypertension and bridging of rural-urban gap. In addition to incidence, increased survival and thereby duration of disease can also be attributed to rise in prevalence. It is important to identify risk factors of such incident hypertension beyond age, in case the tide needs to be stemmed. Previous studies have identified elevated blood pressure (previously known as prehypertension) as a key risk factor, which simply indicates a transition from a normal to hypertensive state. <sup>5 6</sup> Obesity, smoking, alcohol use and dysglycaemia are other reported significant factors in these two studies from India. Lack of physical activity and increase in alcohol use have been identified as key risk factors in two recent meta-analyses. 9 10 The evidence base of incident hypertension and its risk factors is sparse and there is a need to better understand relationships in cohort studies, especially in vulnerable population subgroups.

Two-thirds of population of India is young, and more than half of all adults residing in urban areas are economically disadvantaged. These population subgroups are most vulnerable to develop incident hypertension, contributing to overall CVD burden. The current study is designed to estimate incidence of hypertension and its predictors on follow-up. In addition to project future anticipated burden of disease and identification of vulnerable groups, incidence information is also important to assess operational adequacy of NPCDCS in the envisaged annual follow-up surveys.

#### **METHODS**

#### Design

We established a cohort of adults residing in urban slums of Bhopal to estimate incidence of hypertension. Detailed methods of the study are described in a preprint of manuscript under publication and are available on preprint server. <sup>12</sup>

### Setting

We identified a total of 16 urban slum clusters in Bhopal, a city located in central India. Accredited social health workers (ASHAs), one from each cluster was trained to perform CVD risk assessment, follow-up of the participants and to improve their linkages with public health system. They were supported by a team of study physicians and supervisors, for hand-holding and confirmation of hypertension status.

#### **Participants**

All adults residing in these areas were invited for participation in a baseline cardiovascular risk assessment survey, which was performed between November 2017 and March

2018. The primary purpose of the baseline survey was to identify individuals at higher CVD risk (hypertension, diabetes mellitus) and improve their linkages to primary care facilities. Blood pressure assessment was done at least three times at baseline for diagnosis of hypertension, which was defined as systolic blood pressure (SBP) ≥140 mm Hg or diastolic blood pressure (DBP) ≥90 mm Hg on two or more occasions.

All the participants of baseline survey, who did not have a diagnosis of hypertension, were invited for follow-up. Individuals who were pregnant or those who refused for a follow-up assessment were excluded. There were no other exclusions. Follow-up survey was performed between April and June 2019.

#### **Procedures**

Both baseline and follow-up measurement of blood pressure was performed using the same methodology. We measured blood pressure using a digital sphygmomanometer (Omron digital apparatus, model 7200, Kyoto, Japan) with standard-sized adult cuff. All measurements were done with participants in a sitting position, with well-supported arm and back. An average of three readings obtained 1 min apart was recorded as blood pressure at that time. These measurements were obtained at home by ASHAs. Blood pressure was verified for all individuals who had values for SBP ≥140 mm Hg or DBP ≥90 mm Hg, and for 10% of all other individuals by a trained supervisor. All individuals who had elevated blood pressure had their status verified by a study physician at a primary care facility, before classifying them as having newly diagnosed hypertension.

# Statistical analysis

Baseline data were collected on mobile phone-based application (CommcareHQ), it was then exported in Excel and then cleaned and analysed in R software. 13 Information on baseline variables (age, gender, education, wealth quintiles, smoking status, alcohol consumption, physical activity level, body mass index (BMI), waist circumference, glycaemic status) was abstracted from this dataset. All individuals who did not have a diagnosis of hypertension at baseline, but had their SBP between 120 and 139 or diastolic BP between 80 and 89 were classified as having elevated blood pressure (or prehypertension). All individuals who had their random blood sugar values of 140 mg/dL or greater at baseline were classified as having dysglycaemia. Incidence rate of hypertension and its CI were estimated by using binom<sup>14</sup> package in R software which uses binomial distribution. It is expressed as incidence per 100 person-years of follow-up. The gtsummary<sup>15</sup> package in R software was used to create summary table grouped by presence or absence of incident hypertension. Comparison of distribution of sociodemographic and clinical factors among those who developed incident hypertension and those who did not was done by using  $X^{2}$  or t-test appropriately. Development of incident hypertension in a given time is a binary variable.

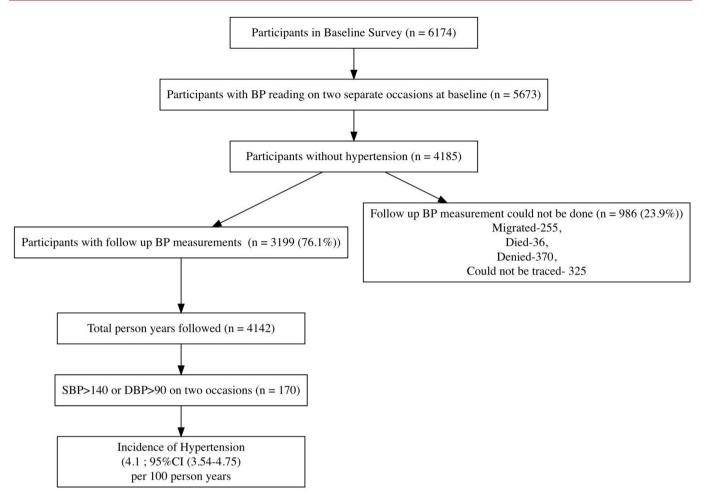


Figure 1 Study flow chart. BP, blood pressure; DBP, diastolic blood pressure; SBP, systolic blood pressure.

To identify the independent predictors of developing incident hypertension, we have performed relative risk (RR) regression by using maximum likelihood regression for log-binomial models;  $logbin^{16}$  package in R software was used for this purpose. The logbin package provides different algorithms for fitting log-link binomial generalised linear model (RR regression), allowing stable maximum likelihood estimation and obeying parameter constraints. We first entered sociodemographic and clinical variables individually to estimate RR and CI while adjusting for follow-up time. Then we have selected variables with p<0.20 for entering in to RR regression model. We have used CEM 'algorithm and 'squarem' method for acceleration in logbin package. Then adjusted RR and its CI are presented in results.

#### **RESULTS**

Of the 6174 participants approached at baseline, two blood pressure readings on separate occasions were available for 5673 participants. Out of these, 4185 participants did not have hypertension at baseline and were considered as cohort base. Of these, 3199 (76.4%) were followed up after a median on 1.25 years (IQR 1.08–1.60) (figure 1). Among this cohort of 3199 individuals, most were below 45 years of age (2013; 62.9%),

were women (1937; 60.5%), had a BMI below 25 kg/m² (1708; 53.4%) and were classified as sedentary (2373; 74.2%) based on leisure time physical activity levels (table 1). Online supplemental table 1 shows comparison of baseline characteristics among those who were followed and who were lost to follow-up. Relatively more men, those belonging to lower wealth quintile, having low BMI and low waist circumference, a non-sedentary lifestyle, tobacco users and alcohol users were more likely to be lost to follow-up.

A total of 170 individuals (5.31%) were detected with a new onset hypertension. New onset hypertension was confirmed only after repeat measurements by the study supervisor and study physician, thus verifying all the elevated blood pressure values obtained by ASHAs. Overall incidence of hypertension was 4.1 (95% CI 3.54 to 4.75) per 100 person-years of follow-up. Incidence was highest in those above the age of 60 years (8.04; 95% CI (5.38 to 11.55)) and lowest in those below 45 years of age (2.61; 95% CI (2.03 to 3.31)) per 100 person-years.

On multivariate analysis, age was a significant predictor of incident hypertension (RR 1.98; 95% CI 1.19 to 3.3, for age >60 years). Those belonging to first and second Wealth Index tertile were having higher risk as compared



 Table 1
 Characteristics of individuals without hypertension (HTN) at baseline, stratified by HTN status on follow-up (n=3199)

Characteristic	Distribution at baseline N=3199/persontime	No HTN on follow-up (n=3029)	Developed HTN on follow-up (n=170)	P value	Incidence rate per 100 person-years of follow-up
	unie	(11-0023)	(11-170)		or ronow-up
Age group <44	2013/2637.99	1944 (97%)	69 (3.4%)	<0.001	2.61 (2.03 to 3.31)
		, ,	, ,		,
45–59	900/1141.16	828 (92%)	72 (8.0%)		6.3 (4.9 to 7.94)
60+	286/360.34	257 (90%)	29 (10%)	0.002	8.04 (5.38 to 11.55)
Gender	1000/1500 70	1170 (000/)	00 (0 00/)	0.003	F 40 (4 07 to C C7)
Men	1262/1582.78	1176 (93%)	86 (6.8%)		5.43 (4.37 to 6.67)
Women	1937/2556.70	1853 (96%)	84 (4.3%)	0.004	3.28 (2.62 to 4.06)
Education	0000/0000 05	0404 (000)	00 (4 00)	<0.001	0.40 (0.50) 0.00)
Literate	2290/3003.95	2194 (96%)	96 (4.2%)		3.19 (2.58to3.90)
Illiterate	909/1135.53	835 (92%)	74 (8.1%)		6.51 (5.11 to 8.18)
Wealth quintiles				0.007	
T1	847/1085.05	791 (93%)	56 (7%)		5.16 (3.89 to 6.70)
T2	986/1242.91	929 (94%)	57 (6%)		4.58 (3.47 to 5.94)
Т3	1216/1644.17	1171 (96%)	45 (4%)		2.73 (1.99 to 3.66)
BMI classification				0.107	
≤18.50	308/394.79	298 (97%)	10 (3.2%)		2.53 (1.21 to 4.65)
18.51-25.00	1400/1849.40	1331 (95%)	69 (4.9%)		3.73 (2.90 to 4.72)
25.01–30.00	663/895.88	625 (94%)	38 (5.7%)		4.24 (3.00 to 5.82)
30.01+	201/267.49	185 (92%)	16 (8.0%)		5.98 (3.41 to 9.71)
Leisure time physical activity				0.815	
Non-sedentary	691/810.48	656 (95%)	35 (5.1%)		4.31 (3.00 to 6.00)
Sedentary	2508/3329.01	2373 (95%)	135 (5.4%)		4.05 (3.40 to 4.79)
Abdominal obesity				0.180	
Non-obese	1654/2075.44	1575 (95%)	79 (4.8%)		3.80 (3.01 to 4.74)
Obese	1541/2059.87	1450 (94%)	91 (5.9%)		4.41 (3.55 to 5.42)
Alcohol		,	,	0.004	,
Non-user	2626/3454.21	2501 (95%)	125 (4.8%)		3.61 (3.01 to 4.31)
User	573/685.28	528 (92%)	45 (7.9%)		6.56 (4.78 to 8.78)
Tobacco	0.0,000.20	020 (0270)	(1.1070)	0.001	
Non-user	2072/2751.27	1982 (96%)	90 (4.3%)	0.00	3.27 (2.63 to 4.02)
User	1127/1388.22	1047 (93%)	80 (7.1%)		5.76 (4.56 to 7.17)
Current smokers	1121/1000.22	1047 (3070)	00 (7.170)	0.375	0.70 (4.00 to 7.17)
Non-smokers	3063/3972.67	2903 (95%)	160 (5.2%)	0.070	4.02 (3.42 to 4.70)
Smokers	136/166.81	126 (93%)	10 (7.4%)		5.99 (2.87 to 11.02)
BP status 2017	100/100.01	120 (30 /0)	10 (7.470)	<0.001	0.00 (2.07 to 11.02)
Normal	1836/2359.26	1792 (070/)	54 (2.09/)	0.001	2.28 (1.71 to 2.98)
		1782 (97%)	54 (2.9%)		, ,
Prehypertension	1363/1780.23	1247 (91%)	116 (8.5%)	0.010	6.51 (5.38 to 7.81)
Dysglycaemia 2017	0750/0504-00	0004 (0500)	1.40 (5.40()	0.616	0.00 (0.05 / 5.55)
Absent	2753/3561.98	2604 (95%)	149 (5.4%)		3.63 (2.25 to 5.55)
Present	446/577.50	425 (95%)	21 (4.7%)	0.505	4.18 (3.53 to 4.91)
Follow-up years	1.25 (1.08–1.60)	1.25 (1.08–1.60)	1.23 (1.09–1.51)	0.532	

BMI, body mass index; BP, blood pressure.

Table 2 Risk of incident hypertension, univariate and multivariate relative risk (RR) regression analysis (n=3199)

Variables	RR (univariable)	RR (multivariable)			
Age group					
<44	Ref	Ref			
45–59	2.33 (1.69 to 3.21, p<0.001)	1.81 (1.22 to 2.67, p=0.003)			
60+	2.95 (1.95 to 4.48, p<0.001)	1.98 (1.19 to 3.3, p=0.008)			
Gender					
Men	1.57 (1.17 to 2.10, p=0.003)	1.4 (0.91 to 2.17, p=0.126)			
Women	Ref				
Education					
Literate	-	-			
Illiterate	1.94 (1.44 to 2.6, p<0.001)	1.9 (1.35 to 2.69, p<0.001)			
Wealth tertiles					
T1	1.78 (1.21 to 2.62, p=0.003)	1.85 (1.17 to 2.91, p=0.008)			
T2	1.56 (1.06 to 2.29, p=0.003)	1.83 (1.18 to 2.83, p=0.007)			
T3	Ref				
Tobacco					
Non-user	Ref	Ref			
User	1.63 (1.21 to 2.19, p=0.001)	1.23 (0.84 to 1.81, p=0.293)			
Alcohol					
Non-user	Ref	Ref			
User	1.64 (1.18 to 2.29, p=0.003)	1.17 (0.73 to 1.88, p=0.51)			
Leisure time physica	al activity				
Non-sedentary	Ref				
Sedentary	1.09 (0.75 to 1.57, p=0.655)	-			
BMI classification					
≤18.50	Ref	Ref			
18.51-25.00	1.53 (0.8 to 2.94, p=0.201)	1.42 (0.74 to 2.74, p=0.291)			
25.01-30.00	1.79 (0.9 to 3.55, p=0.095)	1.86 (0.92 to 3.76, p=0.082)			
30.01+	2.48 (1.15 to 5.35, p=0.021)	2.1 (0.91 to 4.86, p=0.082)			
Abdominal obesity					
Non-obese	Ref	_			
Obese	1.25 (0.93 to 1.69, p=0.134)	-			
BP status (2017-201	8)				
Normal	Ref	Ref			
Elevated	2.91 (2.12 to 3.98, p<0.001)	2.72 (1.83 to 4.03, p<0.001)			
Dysglycaemia (2017–2018)					
Absent	Ref	_			
Present	1.0 (0.64 to 1.56, p=1.00)	-			

BMI, body mass index; BP, blood pressure.

with those in third tertile. Among modifiable risk factors, BMI greater than  $30~{\rm kg/m^2}$  increased the risk of new onset hypertension (RR 2.1; 95% CI 0.91 to 4.86), however it was statistically not significant. Individuals who had an elevated blood pressure at baseline (or prehypertension) had a significantly increased risk of converting to hypertension on follow-up (RR 2.72; 95% CI 1.83 to 4.03). The risk of new onset hypertension was more in individuals who were not literate (RR 1.94; 95% CI 1.31 to 1.86) (table 2).

#### DISCUSSION

We found that incidence of hypertension in urban slums of central India is progressively higher with increasing age, lower Wealth Index tertiles and more in men as compared with women in each age band. Overall, about 4 new hypertensives are likely to be detected for every 100 individuals followed up in a community for a year. In addition to age and Wealth Index tertiles, we found lower education level and elevated blood pressures at baseline as significant predictors of incident hypertension. These features help us to identify vulnerable groups within the urban slum population, who are more at risk. Most concerning of these are individuals who had an elevated blood pressure (also known as prehypertension) at baseline, who are at three times greater risk of converting to new onset hypertension. This group is also numerically largest, constituting about two-fifths of the entire cohort at baseline.

While various studies have reported prevalence of hypertension in India, there are only a limited studies on its incidence. In a study conducted in 2010 from Kerala (a high non-communicable disease-burden state in India), the reported incidence of hypertension was 3.3%. More recently CARRS Study from metropolitan cities of New Delhi, Chennai and Karachi reported a much higher incidence of about 8.2%. These variations could be a reflection of time period of the study, its setting or duration of follow-up. Various pre-2010 studies from China and Korea have reported lower incidence rates of 2.3%, 5.2% and 5.3%, respectively. 17-19 However, in the same time period, incidence rates in North America and Europe were comparatively higher, ranging from 6% to 9% in various age-gender subgroups. 20-22 More recent assessments in the previous decade (table 3) have suggested lower annual incident hypertension rates in studies from communities in Switzerland<sup>23</sup> and Germany<sup>24</sup> (between 2% and 3%), but higher levels (between 8% and 12%) in other studies from China<sup>25</sup> and Germany.<sup>26</sup> Such a heterogeneity indicates dynamicity in incidence rates, indicative of epidemiological transition from lower to higher hypertension prevalence. When higher proportion of individuals are classified as having hypertension, pool of at-risk individuals without hypertension shrinks, accounting for lower incidence. For instance, in a study from Germany, the annual incidence was between 8% and 9% in the first 4 years of follow-up, but reduced to 5%-6% in the subsequent 5 years. 26 It has been observed that incidence rates are lower with longer follow-up periods. With that perspective, of the two previous studies from India, a study from Kerala with 3.3% incidence was a 7-year follow-up from 2003 to 2010, and CARRS Study with 8.2% incidence is a 2-year follow-up from 2015 to 2017. Our study from urban slums of a moderately sized city in India has an intermediate overall incidence rate of 4.45% in a median follow-up duration of 1.25 years.

Illiteracy and lower Wealth Index tertiles indicating socioeconomic position were another significant



Table 3 Estimates and determinants of incident hypertension (HTN) in population-based studies published in the last decade

Study Publication year Country (ref)	Number Follow-up Age range	Reported incidence of HTN	Identified risk factors— multivariate analysis
Rai <i>et al</i> 2020 India <sup>7</sup>	8977 5 years ≥18 years	7.9% in men 5.9% in women	Age
Mohan <i>et al</i> 2020 India <sup>27</sup>	1691 9 years	28.7/1000 person-years	Prehypertension Dysglycaemia Central obesity Physical inactivity
Fidalgo <i>et al</i> 2019 Switzerland <sup>23</sup>	3299 10 years 35–75 years	26.8% over 10 years	Male gender 1.20 (1.07–1.35) Physical activity 0.86 (0.77–0.96)
Prabhakaran <i>et al</i> 2017 India, Pakistan <sup>6</sup>	12 504 2 years 20+ years	82.6/1000 person-years, 95% CI: 80.8 to 84.4	Age Socioeconomic status Current alcohol use Overweight Prehypertension Dysglycaemia
Kumar and Patnaik 2018 India <sup>28</sup>	52 217 12.7 years 17+ years	58.6/100 000 person-years	Cohort was young and from army periodic check-up records and not truly representative of community
Diederichs and Neuhauser 2017 Germany <sup>24</sup>	3045 10+ years 18–79 years	26.2% over 11.9 years	Baseline systolic blood pressure
Lacruz <i>et al</i> 2015 Germany <sup>26</sup>	1436 4 years 45–83 years	8.6 (4.3–12.9) men 5.4 (2.8–10.6) women	
Sun <i>et al</i> 2014 China <sup>25</sup>	20 247 (Han)/4793 (Mongol) 4.2 years 35+ years	9.77/100 person-years (Han) 12.64/100 person-years (Mongol)	Age Prehypertension Body mass index Physical activity
Lee <i>et al</i> 2011 Korea <sup>19</sup>	730 5 years 20+ years	22.9% (95% CI 19.9% to 29.0%) over 5 years	Age >65 years 2.26 (1.21–4.20) Prehypertension 2.25 (1.48–3.42)

predictors of incident hypertension in our study. Smoking and alcohol consumption were also significant on univariate analysis, in our study, but these two are likely to be outcomes of illiteracy and hence intermediary in pathway to causation of hypertension. Previous studies have identified alcohol use as significant risk factor,<sup>6</sup> and a metaanalysis of 20 cohort studies also found that any level of alcohol consumption is associated with increased risk of hypertension (RR 1.51 (95% CI 1.30 to 1.76)) for three to four drinks per day, and 1.74 (95% CI 1.35 to 2.24) for five or more drinks per day in men, and 1.42 (95% CI 1.22 to 1.66) for three or more drinks in women. Obesity, as an indicator of reduced physical activity, was significant predictor on univariate analysis in our study. These two variables have been reported to increase risk of hypertension in recent studies. 6 23 A recent meta-analysis of 22 cohort studies has estimated that in every 10 additional metabolic equivalents of leisure time physical activity,

there is reduced risk of incident hypertension by about 6% (RR 0.94 (95% CI 0.92 to 0.96)). 10

Our results from a vulnerable lower income population add to the evidence base of determinants of incident hypertension from India. We also demonstrate feasibility of establishing a cohort within the public health delivery system, driven by efforts of ASHAs who are community health workers in urban slum communities. Blood pressures at baseline as well as on follow-up were measured by ASHAs, and a comparable incidence with other similar studies validates their measurement skills. Limitation of the study is a shorter period of follow-up, however we have shown that blood pressure change is dynamic, and conversion to a hypertensive state is demonstrable within this interval. Urban slum population is prone to outward migration, as shown in attrition in cohort numbers; however, our overall CIs indicate a reasonable certainty in our point estimates. Results of our study are

generalisable to other similar urban slum populations, who share similar built environments, socioeconomic priorities and vulnerability in terms of access to health-care. We are limited by not being able to generalise our results to other population groups that do not share these attributes.

We believe that ours and other similar studies will be able to strengthen implementation of NPCDCS and help evaluate preventive strategies in shorter time frames. Since diagnosis of hypertension requires lifelong care, our efforts in improving preventive care can be measured in terms of annual incidence of hypertension with each passing year. Such estimates are now feasible within programmatic settings, with implementation of annual blood pressure screening in all adults.

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**Contributors** RJ conceived the study. RJ, APP and SK developed the protocol. AL and NS acquired data, AJ and SK supervised data acquisition, APP, AJ and RJ analysed the data and wrote the first draft. All authors critically reviewed the first draft and provided input for its revisions.

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Competing interests None declared.

Patient consent for publication Not required.

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Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available upon reasonable request to the corresponding author.

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