Indian J Med Res 157, June 2023, pp 498-508
DOI: 10.4103/ijmr.IJMR_389_20

Cost of screening, out-of-pocket expenditure & quality of life for diabetes & hypertension in India

Sehr Brar[1], Gunjeet Kaur[1], Malaisamy Muniyandi[4], Nagarajan Karikalan[4], Henna Bano[1], Anil Bhansali[2], Sanjay Jain[3], Savita Kumari[3] & Shankar Prinja[1]

Departments of [1]Community Medicine & School of Public Health, [2]Endocrinology & [3]Internal Medicine, Postgraduate Institute of Medical Education & Research, Chandigarh & [4]Department of Health Economics, Indian Council of Medical Research-National Institute for Research in Tuberculosis, Chennai, Tamil Nadu, India

Received June 13, 2020

***Background & objectives*: The Government of India has initiated a population based screening (PBS) for noncommunicable diseases (NCDs). A health technology assessment agency in India commissioned a study to assess the cost-effectiveness of screening diabetes and hypertension. The present study was undertaken to estimate the cost of PBS for Type II diabetes and hypertension. Second, out-of-pocket expenditure (OOPE) for outpatient care and health-related quality of life (HRQoL) among diabetes and hypertension patients were estimated.**

***Methods*: Economic cost of PBS of diabetes and hypertension was assessed using micro-costing methodology from a health system perspective in two States. A total of 165 outpatients with diabetes, 300 with hypertension and 497 with both were recruited to collect data on OOPE and HRQoL.**

***Results*: On coverage of 50 per cent, the PBS of diabetes and hypertension incurred a cost of ₹ 45.2 per person screened. The mean OOPE on outpatient consultation for a patient with diabetes, hypertension and both diabetes and hypertension was ₹ 4381 (95% confidence interval [CI]: 3786-4976), ₹ 1427 (95% CI: 1278-1576) and ₹ 3932 (95% CI: 3614-4250), respectively. Catastrophic health expenditure was incurred by 20, 1.3 and 14.8 per cent of patients with diabetes, hypertension and both diabetes and hypertension, respectively. The mean HRQoL score of patients with diabetes, hypertension and both was 0.76 (95% CI: 0.72-0.8), 0.89 (95% CI: 0.87-0.91) and 0.68 (95% CI: 0.66-0.7), respectively.**

***Interpretations & conclusions*: The findings of our study are useful for assessing cost-effectiveness of screening strategies for diabetes and hypertension.**

Key words Cost - complications - diabetes - hypertension - out-of-pocket expenditure - quality of life - screening

Given the rising burden, early age of onset and the associated economic burden of non-communicable diseases (NCDs), the Government of India launched the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS) aiming at prevention as well as early detection and treatment of diabetes, hypertension and common cancers. The objectives of the program are to

prevent and control common NCDs through behaviour and lifestyle changes and provide early diagnosis and management of common NCDs[1]. The focus of NPCDCS was to enable opportunistic screening for common NCDs at secondary care level, through setting up of NCD clinics. Further, population based screening (PBS) for NCDs including diabetes, hypertension and the three common cancers (breast, cervical and oral) has been initiated to complement the NPCDCS at primary care level. PBS is envisaged to address issues of low levels of care-seeking, limited access to health services, reaching marginalized groups, in addition to increasing awareness in the community about NCDs and the need for periodic screening. The process of screening includes active population enumeration, risk scoring on the community based assessment checklist (CBAC) by an accredited social health activist (*ASHA*) and allocation of unique identification number, followed by screening of all individuals above the age of 30 yr at a facility based fixed day camp or through outreach[2].

While screening of NCDs has been initiated at a national level, questions arise related to the most efficient or cost-effective screening methodology. To build evidence for these policy decisions, economic evaluations of different strategies need to be undertaken. The Government of India has established a health technology assessment agency called Health Technology Assessment India (HTAIn) to strengthen evidence based policy making[3,4]. A study was commissioned by the HTAIn to assess the cost-effectiveness of screening for diabetes and hypertension in India. A pre-requisite for such a study involving an economic evaluation for screening strategies for diabetes and hypertension is data on health system costs of screening, out-of-pocket expenditure (OOPE) of patients and health-related quality of life (HRQoL) of diabetes and hypertension patients. While a few studies have been conducted in different parts of the country to assess the implementation of the NPCDCS programme[5,6], cost of implementing the PBS has not been assessed. Second, while the National Sample Survey Organization (NSSO) estimates the nationally representative OOPE for outpatient and inpatient care for different illnesses, it is not possible to classify diabetes and hypertension into those with and without complications. Third, the NSSO data do not specifically provide OOPE for those with comorbidity, *i.e.* diabetes and hypertension, as well as those visiting a tertiary-level hospital. Finally, there is no Indian study on HRQoL of diabetes and hypertension patients using the Euro Quality of Life Questionnaire (EuroQoL), with five dimensions and five-level (EQ-5D-5L) scale tool, which is recommended by the HTAIn for use in economic evaluations.

To address this evidence gap, the current study aimed at determining the health system cost of implementing PBS for diabetes and hypertension, disaggregated OOPE expenditure and HRQoL of patients with diabetes, hypertension, both diabetes and hypertension – both uncomplicated and complicated.

Material & Methods

The study was conducted by the department of Community Medicine & School of Public Health, Postgraduate Institute of Medical Education & Research (PGIMER), Chandigarh, a tertiary care hospital. The study was carried out after approval from the Institute's Ethics Committee. The investigation comprised three parts namely; costing of population based screening (PBS) of diabetes and hypertension, out-of-pocket expenditure (OOPE) and health-related quality of life (HRQoL) of diabetes and hypertension patients. Assessment of OOPE and HRQoL was done by recruiting outpatients from the departments of Endocrinology and Internal Medicine, PGIMER, Chandigarh. An informed written consent was obtained from all participants.

Data collection

Health system costing: An economic costing for PBS of diabetes and hypertension under the NPCDCS (National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases and Stroke) was undertaken using micro-costing methodology and health system perspective[7] in one randomly selected district in the States of Haryana and Tamil Nadu. Within each district, one primary health centre and two sub-centres (SCs) were randomly selected for data collection.

The mode of implementation of PBS varied in both States. In Tamil Nadu, population enumeration and first screening were done door-to-door by a woman health volunteer (WHV) appointed for this purpose. Random blood sugar assessment using glucometer and blood pressure measurement using aneroid blood pressure apparatus were done at household level. In Haryana, the population enumeration and risk scoring were performed by accredited social health activist *(ASHAs)* at household level. The screening of the enumerated population was done in camp mode on a single day involving auxiliary nurse midwives (ANMs) and *ASHAs*.

The data on all resources utilized for the screening of diabetes and hypertension were collected for one-year period using standardized methodology and tools used for economic costing studies of health facilities in India[8-10]. The data on human resources involved in screening included designation, leaves in the reference period and gross annual salary. Time allocation for interview was performed for each of the staff members and further validated using actual observation on the day of the survey. A detailed time motion study was carried out to determine the time contribution of different personnel for individual activities at a screening camp. Data on consumables including quantity and unit price were obtained from the stock register. All the equipment (medical as well as non-medical) used to deliver screening services were also noted along with quantity, unit price, expected average life and maintenance charges during the reference period. The procurement price of each of the inputs was obtained from procurement records in the facility or state health department. In a few items where data were not available, market price was used. Since there was wide variation in the wage rate between the two States, a scenario analysis adjusting for the low wages in Tamil Nadu was also performed. The scenario analysis used average health-care worker wages for India from the National Health System Cost data base[11].

Out-of-pocket expenditure (OOPE) and health-related quality of life (HRQoL): Outpatients from the departments of Endocrinology and Internal Medicine, were assessed for OOPE and HRQoL. Patients who had at least one previous visit, *i.e.* who were diagnosed with either diabetes or hypertension and had been on treatment for one month, were included in the study. A total of 165 patients with diabetes, 300 with hypertension and 497 with both were recruited. Data collection was undertaken over five months from October 2018 to February 2019.

Participants were interviewed to collect data on routine demographic information, consumption expenditure, medical diagnosis, number of facility visits and treatment regimen. Detailed information on OOPE incurred during the last outpatient consultation was collected using standard questionnaires used in previous Indian studies[12,13]. This included expenditure incurred on medicines, diagnostic test, supportive care, procedures, user fees, informal payment and travel and boarding/food in the last visit to the facility in the last one month.

HRQoL was evaluated using the EQ-5D-5L scale[14] and the visual analogue scale (VAS).

Data analysis:

Health system costing: Costs were categorized into two types, namely capital and recurrent costs. In the case of capital items, the annualized cost was estimated using the average lifespan of item and a discount rate of three per cent[15]. Recurrent costs such as personnel salaries, medicines, consumables and overhead expenses were estimated by multiplying price/wage rate and quantity of resource used. Shared costs were apportioned for individual services using appropriate allocation statistics (Table I).

Unit costs were calculated for screening individuals for diabetes and hypertension as per PBS. Further, cost of screening for diabetes and hypertension individually was calculated by classifying costs into two types of screening. Costs of equipment and consumables for each type of screening were considered separately. Costs such as human resource time and supervisory, training and IEC-cost were assumed to be the same, irrespective of type of screening. Pooled unit cost was generated from unit costs of different facilities standardizing for coverage. While adjusting for coverage, equipment, human resources, training cost, IEC cost and supervisory cost were considered as fixed cost and hence kept constant, the variable cost such as consumables and overheads were varied with number of people screened.

OOPE: Mean OOPE expenditure per outpatient consultation was computed. Multiple linear regression was performed to assess the factors associated with OOPE on outpatient care among patients with diabetes and hypertension. The independent variables included in regression were age of the patient, gender, marital status, educational status, employment status, insurance status, wealth quartiles, disease status, presence of complications and disease control status. The model was assessed for multicollinearity and goodness of fit. Results are reported as beta coefficient, confidence intervals (CIs) for odds ratio (O.R.), t test value, *P* value and adjusted *R* square value.

Catastrophic health expenditure (CHE) was computed using a capacity to pay approach[16]. Capacity to pay was defined as the income remaining after meeting basic sustenance needs. To calculate subsistence expenditure, a poverty cut-off was derived as the average food expenditure of households whose

Table I. Data for health system costing of screening for diabetes and hypertension

Input resources	Source of data	Form of data	Methods used to annualize/ annual cost	Allocation criteria used for joint costs
Capital items				
Building/space	Facility observation and measurement	Observation	Estimated the floor size of constructed area multiplied by local commercial rental price	Shared areas apportioned on the basis of duration for which space was used for screening activities
Equipment	Record review (stock register), facility observation	Stock registers	Annualization factor multiplied by purchase price plus annual maintenance cost	Shared equipment costs were apportioned on the basis of the number of individuals screened
Non-consumables (includes table, chair, water cooler, tube lights, *etc*.)	Record review (stock register), facility observation	Stock registers	Annualization factor multiplied by purchase price plus annual maintenance cost	Shared non-consumable items were apportioned on the basis of the number of individuals screened
Recurrent items				
Human resources	Record review, interview, facility observation	Payslips, interviews	Salary multiplied by the proportion of time spent in a year on screening activities	Proportional time spent on various activities
Drugs and consumables (stationery, sanitary items, *etc*.)	Record review	Stock register	Annual amount of drugs/ consumables and price data	Proportion of individuals screened
Overheads utilities				
Electricity	Record review	Monthly electricity bills	Annual consumption of electricity in cardiac centre	Proportional time for which the space was used for screening activities
Water supply	Record review	Monthly water bills	Annual consumption of water in each cost centre	Floor area

food share was in the range of 45th-55th percentile. Subsistence expenditure was adjusted for household size using beta value of 0.56. Capacity to pay was computed as the income remaining after excluding basic sustenance expenditure. Households whose medical expenditure exceeded 40 per cent of the capacity to pay were considered to suffer CHE. Annual OOPE for outpatient care was estimated by taking into account median number of outpatient visits and OOPE on medicine and non-medicine expenses (such as travel, lodging and user free). Frequency of outpatient visits was as reported by patients and was used to estimate the annual number of visits. OOPE on medicine was assumed to be incurred on a monthly basis, while the non-medicine OOPE was incurred only at each outpatient visit.

Annual OOPE on outpatient care = (OOPE for medicine×12)+(non-medicine–related OOPE×median outpatient visits per year)

Binary logistic regression was performed to assess the independent factors determining CHE among patients with diabetes and hypertension. The variables included in regression were age, gender, marital status, educational status, employment status, insurance status, wealth quartiles, disease status, presence of complications and disease control status. The Enter method was used to run the regression model. The model was assessed for multicollinearity and goodness of fit. Results are reported as OR, CIs for OR, Wald's statistic and *P* value.

HRQoL: Health states generated from the scoring on the EQ-5D-5L were converted into utility scores using the Thailand value set[17]. Scoring on the VAS was converted into utility scores by dividing them by 100. Mean scores were generated individually from EQ-5D-5L and VAS, for patients with diabetes, hypertension and both diabetes and hypertension. Scores were also generated for those with and without complications

(such as retinopathy, nephropathy, neuropathy, heart disease, stroke and amputation).

Results

Health system cost of screening: The per capita health system cost of PBS for diabetes, hypertension and both diabetes and hypertension at sub centre level in Haryana was ₹ 92 (US $ 1.32), 70 (US $ 1.00) and 130 (US $ 1.86), respectively, and in Tamil Nadu these were ₹ 22 (US $ 0.31), 13 (US $ 0.19) and 25 (US $ 0.36), respectively. The pooled unit cost of PBS for diabetes, hypertension and both diabetes and hypertension screening at 50 per cent screening coverage was ₹ 38.4 (US $ 0.55), 16.2 (US $ 0.23) and 45.2 (US $ 0.65), respectively (Figure).

In the scenario analysis using a national average wage for healthcare workers in Tamil Nadu, it was observed that the unit cost for screening of diabetes, hypertension and both diseases in Tamil Nadu changed to ₹ 65.7 (US $ 0.94), 56.3 (US $ 0.81) and 80.65 (US $ 1.15) respectively. The adjusted pooled estimates for unit cost of screening of diabetes, hypertension and both diseases were ₹ 53.5 (US $ 0.77), 31.1 (US $ 0.44) and 65.0 (US $ 0.93), respectively.

OOPE: Table II outlines the OOPE per outpatient consultation by socioeconomic and clinical factors. The mean OOPE of a patient with diabetes visiting a tertiary care facility was ₹ 4381 (95% CI: 3786-4976). The mean OOPE for a patient with diabetes with and without complications was ₹ 6007 (95% CI: 3832-8181) and ₹ 3990 (95% CI: 3484-4496), respectively. Similarly, for hypertension, the mean overall OOPE on outpatient consultation was ₹ 1427 (95% CI: 1278-1576), which varied from ₹ 1710 (95% CI: 1198-2223) to ₹ 1392 (95% CI: 1238-1547) among patients with and without complications. It was observed that OOPE was higher among older patients, those belonging to higher richer wealth quintile, those with complications and those with uncontrolled disease status.

The CHE was estimated to have been incurred among 20, 1.3 and 14.8 per cent of the patients with diabetes, hypertension and both diabetes and hypertension, respectively. Further, the percentage of patients experiencing CHE was higher in patients suffering from complications and among those with uncontrolled disease, across the three conditions. An increasing pattern was observed with an increase in the number of complications suffered by patients in both OOPE and CHE (Supplementary Table I).

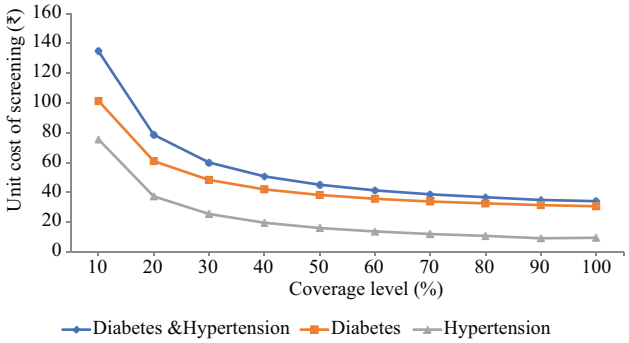


Figure. Unit cost of screening by level of population-wide coverage.

Wealth quartile, disease condition and presence of complications were found to be associated with higher OOPE (P<0.05; Table III). OOPE was significantly lower in patients with hypertension as compared to diabetes patients and patients with both (beta coefficient –0.286, P<0.001).

The odds of incurring CHE was 1.8 times higher in females and those with complications as compared to males and those without complications, respectively (Table IV). The odds of incurring CHE was highest among patients with diabetes and least in patients with hypertension. The odds of incurring CHE was 36.5 times higher in the poorest quintile as compared with the richest quartile (P<0.001).

HRQoL: The mean HRQoL score for diabetes patients with and without complications was 0.61 (95% CI: 0.53-0.69) and 0.8 (95% CI: 0.76-0.84), respectively. Similarly, the mean HRQoL score for patients of hypertension with and without complications was 0.78 (95% CI: 0.76-0.8) and 0.9 (95% CI: 0.88-0.92), respectively, and for those with both diabetes and hypertension with and without complications was 0.62 (95% CI: 0.58-0.66) and 0.72 (95% CI: 0.68-0.76), respectively. The quality of life of patients was lower in patients with complications, patients with uncontrolled disease and patients who were on insulin-based treatment (Table V). Further, the distribution of levels reported of different domains in the tool was also assessed (Supplementary Table II).

HRQoL scores and mean OOPE of patients with different complications are provided in Supplementary Table I.

Discussion

NCDs present a significant public health challenge with adverse health effects and economic burden.

Table II. Out-of-pocket expenditure (OOPE) and catastrophic health expenditure for outpatient care among diabetes and hypertension patients

Factors	n	Mean OOPE (95% CI)	Median	CHE (%)
Socioeconomic factors				
Gender				
Male	494	3230 (2901-3558)	2260	10.5
Female	464	3211 (2940-3481)	2510	12.5
Age				
18-35	66	1883 (1351-2415)	935	6.1
36-45	158	2711 (2062-3359)	1847	7.6
46-55	246	3268 (2859-3676)	2375	13.0
56-65	304	3570 (3193-3948)	2805	11.2
>65	183	3556 (3121-3990)	3000	14.2
Wealth quartile				
I (poorest)	299	2578 (2325-2832)	1960	23.1
II	301	3081 (2786-3367)	2550	3.0
III	163	4192 (3347-5036)	2750	4.3
IV (richest)	107	4184 (3465-4904)	3060	0.9
Clinical factors				
Diabetes	165	4381 (3786-4976)	3500	20.0
Without complications	133	3990 (3484-4496)	3400	18.0
With complications	32	6007 (3832-8181)	3960	28.1
Hypertension	300	1427 (1278-1576)	1010	1.3
Without complications	267	1392 (1238-1547)	1000	1.5
With complications	33	1710 (1198-2223)	1210	0.0
Diabetes and hypertension	497	3932 (3614-4250)	3090	14.8
Without complications	318	3537 (3178-3895)	2945	13.8
With complications	175	4688 (4079-5297)	3290	16.0
Complications				
Absent	718	2823 (2614-3033)	2120	10.2
Present	240	4455 (4241-4669)	3200	15.7
Disease control status				
Controlled	309	3035 (2692-3379)	2185	9.7
Uncontrolled	634	3289 (3016-3562)	2510	12.5
Treatment regimen amongst diabetes and diabetes and hypertension				
Insulin based	257	4889 (4418-5359)	3760	19.5
Oral hypoglycaemics	405	3508 (3169-3848)	2910	13.8
Overall	962	3228 (3015-3441)	2410	11.6

CI, confidence interval; CHE, catastrophic health expenditure

They not only burden the health system but also push households into poverty owing to the requirement of long term management and treatment. To build evidence to inform policies on screening of diabetes and hypertension, information on cost borne by the health system and patients is required. The first year target of the PBS was 50 per cent coverage of target population[2]. The pooled screening cost for diabetes and hypertension at 50 per cent coverage was ₹ 45.2 (US $ 0.65). The unit cost of screening declined with rise in coverage and plateaued at 70 per cent population coverage. A wide variation was observed in screening cost in the two

Table III. Determinants of OOPE for outpatient care among diabetes and hypertension patients

Variable	Standardized beta coefficient	*T*	*P*
Demographic variables			
Gender	−0.011	−0.271	0.786
Age group	0.037	1.09	0.276
Marital status	0.017	0.532	0.595
Education	0.053	1.515	0.13
Employment status	−0.049	−1.11	0.267
Financial variables			
Insurance status	−0.017	−0.472	0.637
Wealth quartile	0.152	4.825	<0.001
Disease classification			
Diabetes	0.1	2.961	0.003
Hypertension	−0.296	−8.152	<0.001
Presence of complications			
Present	0.192	5.922	<0.001
Disease control status			
Glycaemic control	0.029	0.91	0.363
Adjusted R^2: 0.207			

States (Haryana and Tamil Nadu), attributable to the mode of implementation. First, the primary screening in Tamil Nadu was done at household level compared to camp or facility-based mode in Haryana. Second, human resource cost contributed to 75-90 per cent cost in Haryana as compared to 27-35 per cent in Tamil Nadu (Supplementary Figure), as Tamil Nadu employed a single WHV who performed all screening activities and first screening at the household, whereas, in Haryana, *ASHAs* performed population enumeration at household level followed by screening at camps involving both ANMs and *ASHAs*. Further, the remuneration of the WHV was ₹ 3100 per month as compared to salary of ANMs ranging from ₹ 24,000 (contractual) to ₹ 63,000 (permanent) in Haryana, in addition to *ASHAs* who were remunerated on an incentive basis. Third, the screening coverage was much higher in Tamil Nadu (71%) as compared to Haryana (30%), further reducing per capita cost of screening in Tamil Nadu. To account for the considerably lower wages in Tamil Nadu, a scenario analysis with average healthcare worker wages at community level was used to estimate unit cost of screening. It was found that the estimates of the two States became more comparable in this scenario, and the pooled unit cost estimates also increased from ₹ 45.2 (US $ 0.65) to 65 (US $ 0.93). Such differences in the unit cost due to the disparities in wages and prices across different States of India have been highlighted by several other studies[18,19].

The estimates of HRQoL for patients with diabetes were found to be consistent with other studies in Canada, Norway, Japan and the Netherlands, which reported utility scores of 0.76 (95% CI: 0.58-0.94), 0.85 (95% CI: 0.82-0.87), 0.88 (95% CI: 0.85-0.91) and 0.81 (95% CI: 0.8-0.82) among uncomplicated patients and 0.7 (95% CI: 0.5-0.9), 0.73 (95% CI: 0.69-0.78), 0.85 (95% CI: 0.82-0.97) and 0.61 (95% CI: 0.59-0.63) among complicated patients[20-23]. The HRQoL estimates for patients with hypertension in our study were in keeping with a study in Nepal, reporting HRQoL of 0.87 (95% CI: 0.86-0.89) and 0.64 (95% CI: 0.51-0.77) on EQ-5D-3L and VAS, respectively[24]. The quality of life of patients with complications and those with uncontrolled disease was observed to be lower across all disease groups, as reported by a number of other studies[20,22,25], highlighting the need to focus on treatment compliance and prevention of development of complications amongst diabetes and hypertension patients.

The present study also assessed OOPE per outpatient consultation for patients with diabetes and hypertension. Patients with diabetes had the highest OOPE followed by patients with both diabetes and hypertension. While the difference between OOPE amongst diabetes patients and those with both diabetes and hypertension was not statistically significant (*P*=0.176), possible reasons for this difference were explored. The samples of both disease groups were similar in age distribution, socioeconomic status, education, insurance status and other demographic variables. It was noted that the average duration of disease amongst the diabetes group was 21.3 yr as compared with 12.4 yr among the group with both diseases. It has been reported by multiple studies that a longer duration of illness amongst diabetes patients is associated with difficulty in achieving glycaemic control, requirement of more and higher doses of medication[26,27]. Such medication is associated with higher costs. This is reflected by the average monthly OOPE on medicines of patients with diabetes (₹ 2936) and those with diabetes and hypertension (₹ 2500). This is consistent with another study from India which reported that expenditure increased with duration of diabetes[26]. An increasing trend in OOPE was observed with the presence of complications (Table II) and the number of complications (Supplementary Table I);

Table IV. Association of sociodemographic and clinical factors with catastrophic health expenditure for outpatient care

Variable	Categories	Wald's statistic	*P*	OR	OR (95% CI)	
					Lower	Upper
Demographic variables						
Gender	Male			Reference		
	Female	3.098	0.078	1.819	0.934	3.54
Age group	18-35	0.984	0.912	Reference		
	36-45	0.575	0.448	0.573	0.136	2.417
	46-55	0.255	0.613	0.707	0.185	2.711
	56-65	0.09	0.764	0.814	0.213	3.117
	>65	0.061	0.804	0.839	0.21	3.356
Marital status	Married			Reference		
	Unmarried	0.661	0.416	1.457	0.588	3.612
Education	Illiterate	2.523	0.641	Reference		
	Up to primary	1.083	0.298	1.784	0.6	5.308
	Up to secondary	1.676	0.195	1.728	0.755	3.954
	Graduation	0.228	0.633	1.277	0.468	3.485
	Post-graduation	1.296	0.255	2.066	0.592	7.205
Employment status	Employed			Reference		
	Unemployed	0.359	0.549	0.81	0.406	1.616
Financial variables						
Insurance status	Insured			Reference		
	Uninsured	0.037	0.847	1.067	0.551	2.069
Wealth quartile	Richest	63.869		Reference		
	Poorest (I)	12.268	<0.001	36.468	4.874	272.858
	II	1.63	0.202	3.858	0.486	30.65
	III	1.342	0.247	3.568	0.415	30.692
Clinical variables						
Disease condition	Hypertension	29.283	<0.001	Reference		
	Diabetes	29.268	<0.001	23.311	7.449	72.946
	Diabetes + hypertension	20.492	<0.001	12.924	4.268	39.139
Presence of complications	Complications absent			Reference		
	Complications present	3.534	0.06	1.761	0.976	3.175
Disease control status	Controlled			Reference		
	Uncontrolled	0.222	0.637	1.159	0.627	2.143
Treatment	Insulin based			Reference		
	Non-insulin based	10.514	0.001	2.562	1.451	4.523

Hosmer and Lemeshow test: χ^2 3.981; Degrees of freedom 8; Significance 0.859. OR, odds ratio; CI, confidence interval

this was in keeping with other studies that reported expenditure proportionately increasing with the number of complications[28,29]. Furthermore, the input-wise distribution of OOPE was assessed (Supplementary Table III) and majority (63%) of the expenditure was found to be incurred on medicines, which is consistent with a number of other studies in India[28,29].

Policy implications: This study highlights a few operational and programmatic considerations with regard to PBS of diabetes and hypertension. The Tamil Nadu model was observed to have more effective

Table V. Health related quality of life (HRQoL) of diabetes and hypertension patients

Factors	n	Mean $HRQoL_{EQ-5D-5L}$ (95% CI)	n	Mean $HRQoL_{VAS}$ (95% CI)
Socioeconomic factors				
Gender				
Male	488	0.81 (0.79-0.83)	494	0.71 (0.69-0.73)
Female	460	0.72 (0.70-0.74)	464	0.7 (0.68-0.72)
Age				
18-35	66	0.93 (0.89-0.97)	66	0.76 (0.72-0.80)
36-45	158	0.86 (0.82-0.90)	50	0.75 (0.73-0.77)
46-55	244	0.77 (0.73-0.81)	158	0.72 (0.70-0.74)
56-65	300	0.74 (0.70-0.78)	246	0.68 (0.66-0.70)
>65	180	0.67 (0.63-0.71)	183	0.67
Wealth quartile				
I (poorest)	299	0.77 (0.73-0.80)	299	0.71 (0.70-0.73)
II	301	0.76 (0.72-0.80)	301	0.72 (0.70-0.74)
III	163	0.78 (0.74-0.82)	163	0.70 (0.68-0.72)
IV (richest)	107	0.73 (0.68-0.77)	107	0.70 (0.64-0.70)
Clinical factors				
Diabetes	165	0.76 (0.72-0.80)	234	0.7 (0.68-0.72)
Without complications	133	0.8 (0.76-0.84)	178	0.71 (0.69-0.73)
With complications	32	0.61 (0.53-0.69)	56	0.66 (0.60-0.72)
Hypertension	300	0.89 (0.87-0.91)	300	0.77 (0.75-0.79)
Without complications	267	0.9 (0.88-0.92)	267	0.78 (0.76-0.80)
With complications	33	0.78 (0.76-0.80)	33	0.72 (0.66-0.78)
Diabetes and hypertension	418	0.68 (0.66-0.70)	428	0.66 (0.64-0.68)
Without complications	269	0.72 (0.68-0.76)	273	0.68 (0.66-0.70)
With complications	149	0.62 (0.58-0.66)	151	0.62 (0.58-0.66)
Complications				
Absent	710	0.81 (0.79-0.83)	718	0.72 (0.70-0.74)
Present	238	0.64 (0.60-0.68)	240	0.64 (0.62-0.66)
Disease control status				
Controlled	305	0.80 (0.79-0.82)	309	0.72 (0.70-0.74)
Uncontrolled	629	0.75 (0.73-0.77)	634	0.70 (0.68-0.72)
Treatment regimen amongst diabetes and diabetes and hypertension				
Insulin based	257	0.67 (0.63-0.70)	257	0.65 (0.63-0.67)
Oral hypoglycaemics	405	0.74 (0.71-0.76)	405	0.69 (0.67-0.71)
Overall	952	0.77 (0.75-0.79)	962	0.7 (0.68-0.72)

CI, confidence interval; EQ-5D-5L, Euro quality of life questionnaire with five dimensions and five-level scale; VAS, visual analogue scale

implementation in limited resources. The recently announced health and wellness centres (HWCs) under the *Ayushman Bharat* programme[30] could help in smooth implementation of PBS with better coverage and resources. The adverse effects of comorbidity of diabetes and hypertension in terms of poor HRQoL and economic burden was clearly established in the present study, highlighting the importance of screening for both conditions together and continued treatment to prevent progression to complications.

Our investigation, however, had certain limitations. First, the OOPE and HRQoL estimates were generated from a cross-sectional sample drawn from one tertiary level public healthcare facility in north India; thus, the study results could have limited generalizability. However, this facility has patient footfall from more than six Indian States and as a result represents the heterogeneity in terms of geography, rural and urban distribution, severity of disease and socioeconomic status. As a result, there is little possibility of any selection bias resulting from a hospital based sample. Further, the findings of this study do not comment upon prevalence, incidence and long term management of NCDs since it was a one time survey. Long term consequences of the financial hardship should be assessed in future studies using a cohort study design to understand the implications pertaining to individuals and households. Second, the EQ-5D-5L health states were covered into utility scores using the Thailand tariff value set due to the absence of an Indian value set. Third, health system cost data on resources such as training, IEC and supervision were collected using a top-down approach from the state level and apportioned to the facility at which the costing was being performed. Finally, the overall cost of management for diabetes and hypertension would require an assessment of health system costs, which is not the objective of the present study. A more comprehensive assessment of health system costs and OOPE would help in determining the overall economic burden of diabetes and hypertension.

To conclude, the current study findings can be used to further undertake cost-effectiveness analysis to determine the ideal interval of screening, mode of screening and diagnostic test. The cost estimates after incorporation of estimates of health system cost as well may be used for determining the reimbursement package rates under various publicly financed health insurance schemes in India. The present study also highlights the rising economic burden of NCDs, largely borne by the patients, which calls for steps in the direction of health system strengthening such as establishment of HWCs.

***Financial support & sponsorship*:** The study was funded by the Department of Health Research, Ministry of Health and Family Welfare, Government of India.

***Conflicts of Interest*:** None.

References

1. Ministry of Health and Family Welfare, Government of India. *National programme for prevention and control of cancer, diabetes, cardiovascular diseases & stroke (NPCDCS) – Operational Guidelines; 2013*. Available from: *https://main.mohfw.gov.in/sites/default/files/Operational.Guidelines.of.NPCDCS.%28Revised-2013-17%29_1.pdf*, accessed on September 2, 2021.
2. National Centre for Disease Control, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India. *Training module for medical officers for prevention, control and population level screening of hypertension, diabetes and common cancer* (Oral, Breast & Cervical); 2017. Available from: *https://main.mohfw.gov.in/sites/default/files/Training.Module.for.Medical.Officers.for.Prevention%2C.Control.and.Population.Level.Screening.of.NCDs_1.pdf*, accessed on September 2, 2021.
3. Prinja S, Downey LE, Gauba VK, Swaminathan S. Health technology assessment for policy making in India: Current scenario and way forward. *Pharmacoecon Open* 2018; *2* : 1-3.
4. Downey LE, Mehndiratta A, Grover A, Gauba V, Sheikh K, Prinja S, *et al.* Institutionalising health technology assessment: Establishing the Medical Technology Assessment Board in India. *BMJ Glob Health* 2017; *2* : e000259.
5. Kashyap V, Shivaswamy M. Assessment of implementation of the national programme for the prevention and control of cancer, diabetes, cardiovascular diseases, and stroke at subcenters of Belagavi taluka: A cross-sectional study. *Indian J Health Sci Biomed Res* 2019; *12* : 21.
6. Ainapure K, Sumit K, Pattanshetty SM. A study on implementation of national programme for prevention and control of cancer, diabetes, cardiovascular diseases and stroke in Udupi district, Karnataka. *Int J Community Med Public Health* 2018; *5* : 2384-7.
7. Drummond M, Sculpher M, Torrance G, O'Brien B, Stoddart G. *Methods for the economic evaluation of health care programme*, 3rd ed. Available from: *https://pure.york.ac.uk/portal/en/publications/methods-for-the-economic-evaluation-of-health-care-programme-third-edition(e43f24cd-099a-4d56-97e6-6524afaa37d1)/export.html*, accessed on September 2, 2021.
8. Sangwan A, Prinja S, Aggarwal S, Jagnoor J, Bahuguna P, Ivers R. Cost of trauma care in secondary- and tertiary-care public sector hospitals in North India. *Appl Health Econ Health Policy* 2017; *15* : 681-92.
9. Prinja S, Sharma Y, Dixit J, Thingnam SKS, Kumar R. Cost of treatment of valvular heart disease at a tertiary hospital in North India: Policy implications. *Pharmacoecon Open* 2019; *3* : 391-402.
10. Prinja S, Gupta A, Bahuguna P, Nimesh R. Cost analysis of implementing mHealth intervention for maternal, newborn & child health care through community health workers: Assessment of ReMIND program in Uttar Pradesh, India. *BMC Pregnancy Childbirth* 2018; *18* : 390.
11. Prinja S, Chauhan AS, Rajsekhar K, Downey L, Bahuguna P, Sachin O, *et al.* Addressing the cost data gap for universal healthcare coverage in India: A call to action. *Value Health Reg Issues* 2020; *21* : 226-9.
12. Prinja S, Bahuguna P, Duseja A, Kaur M, Chawla YK. Cost of intensive care treatment for liver disorders at tertiary care level in India. *Pharmacoecon Open* 2018; *2* : 179-90.
13. Prinja S, Kaur G, Gupta R, Rana SK, Aggarwal AK. Out-of-

pocket expenditure for health care: District level estimates for Haryana state in India. *Int J Health Plann Manage* 2019; *34* : 277-93.

14. The EuroQol Group. *EQ-5D-3L valuation*. Available from: *https://euroqol.org/eq-5d-instruments/eq-5d-3l-about/valuation/*, accessed on September 2, 2021.
15. Wilkinson T, Sculpher MJ, Claxton K, Revill P, Briggs A, Cairns JA, *et al.* The international decision support initiative reference case for economic evaluation: An aid to thought. *Value Health* 2016; *19* : 921-8.
16. Xu K, Evans DB, Kawabata K, Zeramdini R, Klavus J, Murray CJ. Household catastrophic health expenditure: A multicountry analysis. *Lancet* 2003; *362* : 111-7.
17. Pattanaphesaj J, Thavorncharoensap M, Ramos-Goñi JM, Tongsiri S, Ingsrisawang L, Teerawattananon Y. The EQ-5D-5L valuation study in Thailand. *Expert Rev Pharmacoecon Outcomes Res* 2018; *18* : 551-8.
18. Bahuguna P, Guinness L, Sharma S, Chauhan AS, Downey L, Prinja S. Estimating the unit costs of healthcare service delivery in India: Addressing information gaps for price setting and health technology assessment. *Appl Health Econ Health Policy* 2020; *18* : 699-711.
19. Prinja S, Chauhan AS, Bahuguna P, Selvaraj S, Muraleedharan VR, Sundararaman T. Cost of delivering secondary healthcare through the public sector in India. *Pharmacoecon Open* 2020; *4* : 249-61.
20. O'Reilly DJ, Xie F, Pullenayegum E, Gerstein HC, Greb J, Blackhouse GK, *et al.* Estimation of the impact of diabetes-related complications on health utilities for patients with type 2 diabetes in Ontario, Canada. *Qual Life Res* 2011; *20* : 939-43.
21. Solli O, Stavem K, Kristiansen IS. Health-related quality of life in diabetes: The associations of complications with EQ-5D scores. *Health Qual Life Outcomes* 2010; *8* : 18.
22. Sakamaki H, Ikeda S, Ikegami N, Uchigata Y, Iwamoto Y, Origasa H, *et al.* Measurement of HRQL using EQ-5D in patients with type 2 diabetes mellitus in Japan. *Value Health* 2006; *9* : 47-53.
23. Redekop WK, Koopmanschap MA, Stolk RP, Rutten GE, Wolffenbuttel BH, Niessen LW. Health-related quality of life and treatment satisfaction in Dutch patients with type 2 diabetes. *Diabetes Care* 2002; *25* : 458-63.
24. Ghimire S, Pradhananga P, Baral BK, Shrestha N. Factors associated with health-related quality of life among hypertensive patients in Kathmandu, Nepal. *Front Cardiovasc Med* 2017; *4* : 69.
25. Javanbakht M, Abolhasani F, Mashayekhi A, Baradaran HR, Jahangiri Noudeh Y. Health related quality of life in patients with type 2 diabetes mellitus in Iran: A national survey. *PLoS One* 2012; *7* : e44526.
26. Haghighatpanah M, Nejad ASM, Haghighatpanah M, Thunga G, Mallayasamy S. Factors that correlate with poor glycemic control in type 2 diabetes mellitus patients with complications. *Osong Public Health Res Perspect* 2018; *9* : 167-74.
27. Khattab M, Khader YS, Al-Khawaldeh A, Ajlouni K. Factors associated with poor glycemic control among patients with type 2 diabetes. *J Diabetes Complications* 2010; *24* : 84-9.
28. Ramachandran A, Ramachandran S, Snehalatha C, Augustine C, Murugesan N, Viswanathan V, *et al.* Increasing expenditure on health care incurred by diabetic subjects in a developing country: A study from India. *Diabetes Care* 2007; *30* : 252-6.
29. Pushparani JP, Paulin G. Out-of-pocket expenditure on diabetes care in an urban population of Tamil Nadu: A community based study. *Int J Adv Community Med* 2019; *2* : 125-30.
30. Ministry of Health & Family Welfare, Government of India. *Ayushman Bharat-Health and Wellness Centre*. Available from: *https://ab-hwc.nhp.gov.in/*, accessed on September 2, 2021.

For correspondence: Dr Shankar Prinja, Department of Community Medicine and School of Public Health, Postgraduate Institute of Medical Education and Research, Chandigarh 160 012, India
e-mail: shankarprinja@gmail.com

Supplementary Table I. Mean out-of-pocket expenditure (OOPE) and health-related quality of life (HRQoL) of diabetes and hypertension patients with complications

Complication	n	Mean OOPE	95% CI		Mean QoL (EQ-5D-5L)	95% CI		Mean QoL (VAS)	95% CI	
			Lower limit	Upper limit		Lower limit	Upper limit		Lower limit	Upper limit
One complication										
Retinopathy	63	3536	2768	4304	0.71	0.68	0.74	0.67	0.62	0.72
Neuropathy	16	3095	976	5214	0.55	0.48	0.62	0.60	0.49	0.71
Heart disease	56	3926	3074	4779	0.71	0.68	0.74	0.67	0.63	0.72
Stroke	3	4340	2466	6214	0.67	0.45	0.88	0.73	0.67	0.80
Nephropathy	41	5391	3318	7465	0.64	0.59	0.70	0.66	0.61	0.72
Foot ulcer	17	5472	3635	7309	0.48	0.42	0.55	0.60	0.52	0.69
Foot amputation	2	3810	1948	5672	0.49	0.52	0.65	0.53	0.52	0.58
Any one complication	198	4176	3967	4385	0.66	0.62	0.7	0.73	0.71	0.74
Two complications										
Heart disease and retinopathy	5	5064	2078	8050	0.55	0.20	0.91	0.58	0.54	0.62
Amputation and foot ulcer	1	1350	-	-	1.00	-	-	0.75	-	-
Foot ulcer and retinopathy	3	5027	4862	5192	0.75	0.50	1.00	0.65	0.50	0.80
Heart and foot ulcer	1	2000	-	-	0.39	-	-	0.60	-	-
Heart and nephropathy	5	6326	1869	10,783	0.56	0.23	0.78	0.68	0.58	0.78
Heart and neuropathy	1	3500	-	-	0.17	0.22	0.89	0.50	-	-
Heart and stroke	3	3790	1701	5879	0.74	0.60	0.89	0.58	0.50	0.67
Nephropathy and neuropathy	3	3823	1339	6307	0.44	0.35	0.53	0.65	0.39	0.91
Nephropathy and retinopathy	6	9717	4406	15,027	0.62	0.56	0.67	0.53	0.30	0.75
Neuropathy and retinopathy	3	2240	1950	2530	0.71	0.57	0.86	0.57	0.11	1.02
Any two complications	31	5379	3830	6927	0.61	0.5	0.72	0.6	0.53	0.67
Multiple complications										
Heart, amputation and foot ulcers	1	9110	-	-	-0.14	-	-	0.50	-	-
Heart, nephropathy and retinopathy	2	9470	4296	14,644	0.53	0.51	0.55	0.55	0.45	0.65
Heart, nephropathy and stroke	1	9000	-	-	-0.17	-	-	0.25	-	-
Heart, neuropathy and retinopathy	1	2000	-	-	0.59	-	-	0.70	-	-
Nephropathy, neuropathy and retinopathy	3	5133	3420	6847	0.60	0.57	0.63	0.57	0.44	0.70
Nephropathy, neuropathy and stroke	1	1210	-	-	0.26	-	-	0.60	-	-
Nephropathy, retinopathy and amputation	1	3750	-	-	0.27	-	-	0.75	-	-
Nephropathy, retinopathy, heart, amputation and foot ulcer	1	16,000	-	-	0.41	-	-	0.40	-	-
Three or more complications	11	6855	6728	6983	0.35	0.18	0.51	0.55	0.46	0.63

CI, confidence interval; QoL, quality of life; EQ-5D-5L, Euro quality of life questionnaire with five dimensions and five-level scale; VAS, Visual analogue scale

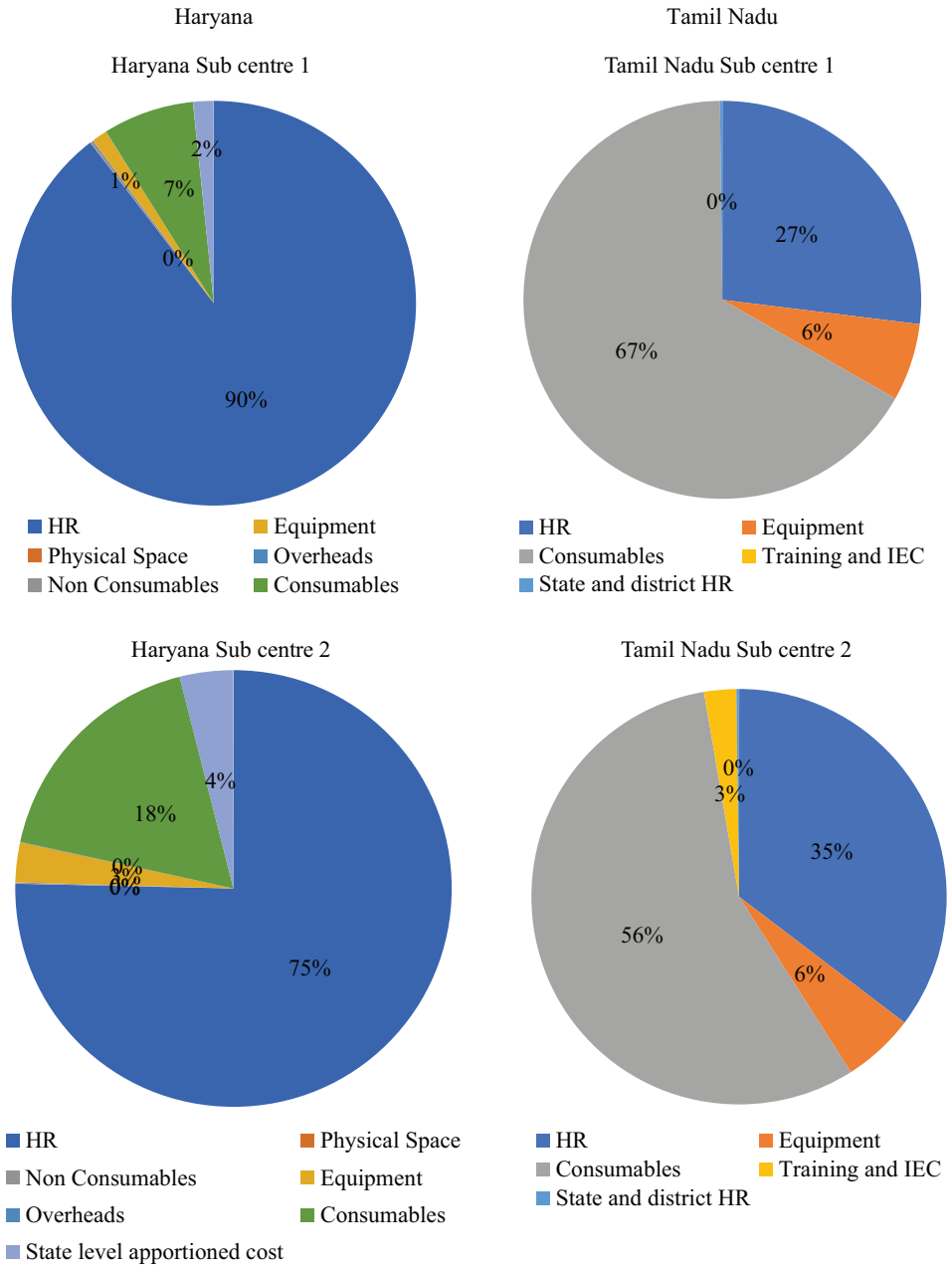
Supplementary Table II. Distribution of diabetes and hypertension patients reporting levels 1-5 in 5 domains of the Euro quality of life questionnaire with five dimensions and five-level scale tool

Level	Mobility, n (%)	Self-care, n (%)	Usual activities, n (%)	Pain, n (%)	Anxiety, n (%)
			Diabetes		
1	149 (65)	181 (79)	152 (66)	123 (53)	173 (75)
2	36 (16)	35 (15)	42 (18)	55 (24)	41 (18)
3	29 (13)	8 (3)	24 (10)	32 (14)	14 (6)
4	15 (6)	6 (3)	5 (2)	16 (7)	2 (1)
5	2 (1)	0 (0)	7 (3)	5 (2)	1 (0)
			Hypertension		
1	237 (79)	268 (89)	251 (84)	228 (76)	290 (97)
2	52 (17)	30 (10)	45 (15)	65 (22)	7 (2)
3	9 (3)	2 (1)	3 (1)	5 (2)	1 (0)
4	2 (1)	0 (0)	1 (0)	2 (1)	1 (0)
5	0 (0)	0 (0)	0 (0)	0 (0)	1 (0)
			Diabetes and hypertension		
1	187 (44)	316 (75)	232 (55)	187 (44)	290 (69)
2	143 (34)	79 (19)	114 (27)	139 (33)	97 (23)
3	60 (14)	19 (4)	36 (8)	61 (14)	30 (7)
4	28 (7)	9 (2)	20 (5)	30 (7)	5 (1)
5	6 (1)	1 (0)	22 (5)	6 (1)	0 (0)
			Overall		
1	573 (60)	765 (80)	635 (67)	538 (56)	753 (79)
2	231 (24)	144 (15)	201 (21)	259 (27)	145 (15)
3	98 (10)	29 (3)	63 (7)	98 (10)	45 (5)
4	45 (5)	15 (2)	26 (3)	48 (5)	8 (1)
5	8 (1)	1 (0)	29 93)	11 (1)	2 (0)

Supplementary Table III. Component distribution of OOPE among diabetes and hypertension patients

OOPE component	Diabetes	Hypertension	D and HTN	Overall
Travel	0.13	0.27	0.18	0.17
Medicines	0.68	0.62	0.59	0.64
Lab diagnostics	0.16	0.10	0.19	0.16
Supportive care procedures	0.000	0.000	0.004	0.002
User fee/hospital charges	0.001	0.005	0.002	0.002
Informal payments	0.000	0.000	0.000	0.000
Boarding/lodging/food	0.02	0.01	0.03	0.02
Other expenses	0.00	0.00	0.00	0.00

OOPE, out-of-pocket expenditure; D, diabetes; HTN, hypertension



Supplementary Figure. Input-wise distribution of screening cost in sub-centres of Tamil Nadu and Haryana.