Improving Access to Medicines for Non-Communicable Diseases in Rural Primary Care: Results from a Cluster Randomised Trial in a District in South India

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**Research article**

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Abstract

Background

A large proportion of non-communicable diseases (NCD) are treatable within primary health care (PHC) settings in a cost-effective manner; however, dependence on PHCs for NCD care is comparatively low in India. The Access to Medicines (ATM) study examined the effect of a community-level and health service level package of interventions on improving availability of generic medicines at PHCs and decreasing expenditure on medicines.

Method

A baseline-endline quantitative experimental approach was used to assess effectiveness of the intervention (18 months) implemented across all 39 rural PHCs of three sub-districts of Tumkur district in southern Karnataka, India. Intervention consisted of three arms with A & B consisting of package of interventions aimed at health service delivery optimization within PHC, and strengthening community platforms respectively; C was the control arm. A cluster randomised household survey was used to understand health seeking behaviour, access and out-of-pocket expenditure (OOP) on key anti-diabetic and anti-hypertension medicines; similarly, facility surveys across these PHCs were conducted to assess availability of medicines. Primary outcomes of the study are mean number of days of availability of medicines, mean number of patients obtained medicines from PHC, OOP expenses and mean number of days for which medicines were procured.

Result

Below 50% of patients only sought care from PHCs in intervention arms and around 30% who visited got patient health records. Mean number of days of key NCD medicines availability at home did not show statistically significant differences across study arms. There was overall increase in mean days of availability of key NCD medicines at PHCs across all study arms. Although there was an overall decrease in OOP on NCD medicines and increase in number of patents visiting PHC for NCD medicines between intervention arms and control from baseline to endline the difference was not statistically significant.

Conclusion

The intervention effects were not uniform within the study groups. Depending on local context some PHCs were able to overcome health system barriers better than the others. Health service interventions at PHC and community level could be hindered by wider health system challenges beyond control of localized study interventions.

Trial Registration

Trial registration number CTRI/2015/03/005640. Retrospectively Enrolled

Background

India accounts for the largest share (66%) of deaths from non-communicable diseases (NCDs) in the South-East Asian Region(1). Even within the country, NCDs are estimated to have contributed to 5.8 million deaths (61% of all deaths) in 2017(2). Despite a relatively good economic growth rate (7–8% annually), demographic, social and epidemiological transitions have contributed to increase in NCD prevalence both in rural-urban(1, 3), rich-poor(4–6) and old and young population(7). Rising NCDs also translate into high healthcare visits and expenses; 40% of all hospital visits and 35% of all out-patient visits in the country(8, 9). In terms of economic impact of NCDs, India is estimated to have lost $237 billion (in 1998 constant international dollars) between 2006 and 2015 from premature deaths due to heart disease, stroke, and diabetes; in fact, deaths from cardiovascular disease alone in India account for the ‘highest loss in potentially productive years of life’ of all countries in the world(10). As per the National Health Accounts of India, out-of-pocket (OOP) expenditure accounts for 64% of the total health expenditure in 2016(11); a higher portion(55%) of these payments was on outpatient care mostly for purchasing medications. OOP expenditure associated with NCDs is often higher than for other conditions and leads to catastrophic expenses for many families who are around poverty line. A 2012 study in southern India reported, 70% of households made OOP payments for outpatient care, and 16% suffered financial catastrophe. OOP spending doubled the number of people living below poverty line in the study area in one month(12).

A large proportion of NCDs are treatable within primary health care settings in a cost-effective manner and associated morbidity and mortality are preventable(13). The principles of integration, community participation and opportunities of intersectoral collaboration offered by the primary health care approach are well-suited to address such conditions (14). Primary health centres(PHCs) are often the first point of care for the patient, and therefore are strategically very important in reaching larger populations with minimal resources. The government of India launched the National NCD programme called the National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke (NPCDCS) in the year 2008. The NCD programme aims to integrate health promotion, early diagnosis, treatment and referral, and further facilitate partnerships with the private sector in order to address rising burden of NCDs(15). Various health system readiness issues have been posited as possible reasons for poor availability and utilisation of NCD care at PHCs (16–21). Despite their widespread distribution and recent high-level commitments to provide NCD care at PHCs(22, 23), the dependence on PHCs for NCD care is comparatively low in India(24).

The Access to Medicines (ATM) study was implemented to examine the effect of a community-level and health service level package of interventions on improvement in NCD care at PHC settings of a rural district in southern Karnataka(25). The study sought to apply a health systems lens in order to understand if (and how) improvement of NCD care in PHCs could result in decreasing OOP on medicines. Using iterations of qualitative inquiry, we have earlier(26, 27) explored possible contextual factors that affect implementation and effectiveness of interventions in the ATM study. In this paper, the results of the effectiveness of the ATM interventions are presented.
Methods

Study objectives

To examine the effects of ATM interventions consisting of a package of community-level and health services level interventions implemented in government primary health centres (PHC) in three regions of a south Indian district on:

1. Improvement in availability of quality generic medicines at PHCs
2. Improvement in access and utilisation of medicines among patients with NCDs
3. Reduction in out-of-pocket expenses among patients with NCDs

Study setting

The study was implemented across PHCs of three talukas (administrative sub-divisions of districts): Sira, Koratagere and Turuvekere of Tumkur district in southern Karnataka. Tumkur is the second largest district in the state with an area of 10,598 square kilometres and has a population of 2.67 million of which about 30% were in urban areas in 2011(28). Tumkur is comparable to many other districts in the country in terms of a mix of government and private (ranging from single doctor clinics to corporate chains of secondary and tertiary level hospitals), formal and informal healthcare providers. In terms of socioeconomic and development indicators, Tumkur could be classified as being one of the average performance district among the 30 districts of Karnataka state(29). The rationale behind selecting Tumkur as the study district, health services structure in Tumkur and characteristics of the government and private health care system in this district are described in detail in the study protocol(30).

Following a rapid assessment of the performance of the local health system at the taluka level using health systems dynamics framework by Olmen et al(31), three talukas (of the 10) were excluded for not having the necessary system preparedness for the intervention. Of the remaining seven talukas, we randomly selected three talukas assuming that PHCs within these talukas will all have comparable levels of readiness for implementing interventions proposed in the ATM study. The selection process is described in detail in the protocol(30). All 39 PHCs across the three selected talukas were randomly allocated to one of three intervention arms of the study in 1:1:1 ratio.

Randomisation, Allocation Concealment and Blinding

PHCs were randomised using a simple random sampling method. PHC enrolment and assignment to intervention arms was done based on the random numbers generated using an open source tool (random.org). The random allocation sequence was initially concealed to the researchers before the intervention was assigned to each of the three study arms. All 39 PHCs were numbered from 1 to 39. Random numbers between 1 to 39 were generated using the open source tool. Each generated random number was kept sequentially inside the three envelopes numbered from 1 to 3. After the allocation was over, intervention was decided for each of the three envelopes as study arm A, B or Control arm. The allocation was concealed to the researchers as well as participants (providers at PHC and patients) before the intervention was assigned. Researcher A generated the random numbers, Researcher B sequentially allocated the random numbers generated to one of the three envelopes and at a later point of time a third researcher (Researcher C) assigned intervention to each of the numbered envelopes. During this process, all three researchers were unaware/blinded of each other's activity. However, after assignment of intervention happened for the PHCs, all researchers knew the assignment but providers and patients stay blinded to this assignment.

Study design and tools

ATM study was a mixed methods study with a baseline-endline quantitative experimental approach to assess effectiveness and a qualitative theory-driven inquiry to explore implementation process and contextual factors. In this paper, we present results only from the quantitative part of the study. Results from qualitative part has been published elsewhere(27,32).

The quantitative cluster randomised trial is a before-after experimental design and focussed mainly on identifying the determinants of improved (if any) access to medicines for diabetes and hypertension. For this we used a cluster randomised household survey to understand the health seeking behaviour, access and expenditure on anti-diabetic and anti-hypertension medicines. We conducted a before-after survey across PHCs to assess availability of key anti-diabetic and anti-hypertensive medicines in the previous year.

For household and facility level surveys, we used adapted versions of standardised World Health Organisation (WHO) survey tools for household survey and Level II facility survey tool respectively, from the WHO operational Packages for Monitoring and Assessing Country Pharmaceutical Situations(33). The tools were finalised after two rounds of piloting at PHCs in an adjacent district by trained data collectors. In addition to the household and facility survey, quarterly visits to PHCs were made to collect data on the implementation of the intervention. We prepared narrative reports of each visit; key insights from these reports were compiled and analysed. We also conducted a quality test on two key anti-diabetic and two anti-hypertensive medicines (two). Generic and branded medicines were sampled from both government and private facilities across the study talukas. While the details of such medicines sampling and medicine quality tests could be accessed from study protocol paper(30), results of the quality tests are published elsewhere(32).

Household survey sampling strategy

Houses with a patient self-reporting either diabetes and/or hypertension were selected. We followed a longitudinal cohort approach. However, we measured outcomes for not exactly the same cohort of patients at baseline and endline. We followed a sample replacement strategy at the endline survey. For patients that were lost to follow-up in the endline survey, we replaced with new patients in the across the three study arms. Sampling strategy is described in detail in additional file 1.
Intervention

The intervention commenced in May 2014 and was implemented over 18 months till November 2015. The intervention PHCs were randomly allocated to one of the three intervention arms. The PHCs in arm A received a package of interventions aimed at health service delivery optimization, arm B consisted of package of interventions aimed at strengthening community participation platforms in addition to interventions in arm A and PHCs in arm C received no intervention other than those that are being implemented in all government PHCs.

Arm A package of interventions included training of PHC staff (doctors, pharmacists, laboratory technicians, staff nurses) on standards treatment protocols for diagnosis and management of diabetes and hypertension, technical support for introduction of patient-retained medical records and PHC-based records for registration and follow-up of diabetes and hypertension patients, advocacy and coordination at state, district and taluka level to ensure continuous supply of medicines to the PHCs and regular outreach visits to PHCs by field staff. Arm B package of interventions included development and dissemination of awareness materials, formation of patient groups, and meeting with Arogya Raksha Samiti (ARS) members on matters related to diabetes and hypertension care. Further details of the package of activities for the intervention and how they were developed are available in the study protocol(30).

Hypothesis

Improvement in availability of quality generic medicines at PHCs, access and utilisation among patients with NCDs and reduction in out-of-pocket expenses could be achieved through a package of community-level and health services level interventions.

Measures

The study measures were briefly categorised into dependent variables or outcome indicators and independent socio-demographic variables.

Dependent variables

The primary outcome indicators were measured at both facility and individual levels. Facility level indicators include mean number of days of availability of key generic NCD medicines at PHC and individual level indicators are mean number of patients using PHCs for medicines, OOP expenses among patients with NCDs and mean number of days for which medicines were procured by patients. Secondary outcome indicators are proportion of PHCs compliant to standard treatment guidelines, proportion of PHCs where a trained doctor was available throughout the intervention period, proportion of PHCs where a trained pharmacist was available throughout the intervention period, proportion of PHCs where a functional laboratory was there, proportion of PHCs with NCD registers, proportion of PHCs with an active NCD patient group, proportion of ARS meetings where NCD agenda was discussed and proportion increase in patient awareness on generic drugs.

Independent variables

Socio-demographic variables such as age, sex, marital status, occupation, disease conditions, education and monthly income are the independent variables.

Data management and analysis

Epidata was used for data entry. 10% of the data was randomly verified by the supervisor for quality. In case of systematic errors, the remaining forms were also verified and corrected. Data was then exported from Epidata to Microsoft Excel and final data cleaning was completed. The dataset is available (see data availability statement).

We used SPSS (Statistical Package for Social Science) for data analysis (SPSS version 20). Three datasets were created from the household survey to capture basic household, demographic and patient (NCD) level characteristics. These datasets were joined and the final dataset was validated. Private facility interview data and PHC interview data were appended after cleaning. Exit interview data were analysed separately. Apart from the univariate and bi-variate analysis, we analysed the intervention effect using an intention-to-treat analysis. Independent variables such as socio-demographic characteristics were compared to assess comparability across intervention arms, using t-test and chi-square statistics at baseline and end-line.

The randomisation is at the PHC level for delivery of intervention. We used the intention to treat analysis approach to analyse differences in outcomes across three intervention arms based on assumption of negligible amount of crossover events. Reach to each component of the facility interventions and the community interventions was analysed separately. We also assessed the reach of the intervention in terms health service utilization among NCD patients whom we were able to follow-up from baseline to endline. We analysed efficacy of the intervention for each study outcomes through difference-in-difference analysis using STATA version 12. We compared effectiveness in outcomes for individual patients in Intervention A PHCs, Intervention B PHCs and those from control PHCs. Similarly, we calculated differences in facility level outcome between intervention and control PHCs. Information on drug availability was obtained from the PHC medicine registers. Stock out were assessed for a period of 365 days preceding the date of visit to the PHC. Mean availability days in a year for two key anti-diabetic medicines (Metformin 500 mg tablet and Glibenclamide 5 mg tablet) and two anti-hypertensive medicines (Amlodipine 5 mg tablet and Atenolol 50 mg tablet) was compared across intervention arms. For each PHC, the maximum number of drug availability days was considered for anti-diabetic and anti-hypertensive drugs. Mean and standard errors were estimated by linear regression as part of the difference-in-difference analysis. In addition to calculating the unadjusted difference-in-differences, we used covariates such as: taluka, cluster, age, gender, education, occupation, home to PHC distance, and types of disease (diabetes, hypertension, both these diseases) to calculate adjusted difference-in-differences in outcomes. The research team visited each PHC (including the control PHCs for routine observation) at least thrice during the intervention period. Total number of routine visits made to all PHCs during intervention was 106. We found that few PHCs (six out of total 39) performed better than the others. These PHCs mainly had stable, motivated staff with keen interest towards providing NCD care. Observations from these visits were instrumental in describing role of predictors in reach and effectiveness of the intervention.
Ethical considerations

Ethics clearance was obtained from the WHO ethics review committee and institutional ethics committee of Institute of Public Health, Bangalore (India). We also sought permission from the state department of health and family welfare for implementing the intervention and collecting facility-level data from PHCs. Informed written consent was sought from all participants of the surveys. The participation in the survey was voluntary and no compensation was provided to the participants. All personally identifying information was removed from datasets and manuscript to ensure confidentiality.

Results

The baseline survey was conducted in 1069 households across all 39 PHCs across three talukas: Sira, Koratagere and Turuvekere (13 PHCs each in three arms: A, B and C). We were able to re-survey 96% patients from baseline with 4% lost to follow-up (Fig. 1); a total of 327 patients were newly recruited to the study at the end-line survey. The number of patients finally considered for analysis across three study arms in the follow-up survey is presented below (Fig. 1). We have retained the original group allocation of PHCs across study arms in the final analysis; however, number of patients belonged to each of these study arms in the endline were different from baseline.

The PHC enrolment and establishing baseline took around 6 months’ time. Intervention was implemented over 18 months (May 2014 till November 2015). The trial ended around mid-2016 as the three years’ research came to an end as per the funding grant agreement.

The baseline and end-line study population were comparable in terms of socio-demographic characteristics (see Table 1). The households were also comparable in terms of their possession of assets (two wheelers, fan, television sets) and amenities (tap water, electricity etc.). Geographical access had marginally improved during two years’ period from baseline to end-line survey. 36% respondents said they took more than an hour to reach government hospital (43%, baseline). Median monthly income improved across all three arms; compared to baseline (Table 1). The health expenditure on NCD medicines also increased during this period.

We found monthly household level income increased across study arms from baseline to end-line; while median household income in a year increased from 36000 Indian rupees (514 US$ approx. as on 10th Oct 2019) to 72000 rupees (1029 US$) in arm A, it increased from around 48000 rupees (686 US$) to 84000 rupees (1200 US$) in arm B. In the control arm it increased from 36000 rupees (514 US$) to 84000 rupees (1200 US$).

Reach of the Intervention

Reach to the intervention was below par especially for the community-level package of interventions (Fig. 2a). 49% of patients sought care from PHCs during intervention period in intervention arm A compared to 47% in arm B. While patients in B arm (25%) fared better in terms of obtaining medicine from PHCs, for A arm it was low (16%). The follow-up profile of patients who reached intervention PHCs is presented in Fig. 2b.

Effectiveness of the intervention

Mean availability of key NCD medicines at home was relatively better in intervention arms A and B than patients in control arm although the difference was not statistically significant. Patients in Sira and Koratagere taluka had better availability than patients in Turuvekere. Similarly, nearly 60% of patients in Sira and Koratagere visited their PHCs while it was only 40% for Turuvekere. Mean number of days of medicines availability with the patients did not differ at all going from baseline to follow up across study arms. Irrespective of intervention and intervention period, the median days of availability of medicines at home stayed at 20 days. Effect of the two major interventions (health system optimisation and community platform strengthening) on key study outcomes was explained below (Table 2).

Health system optimization

We found that there was overall increase in mean days of availability of anti-diabetic drug and anti-hypertensive medicines at PHCs from baseline to end-line but the increase was across all study arms (Table 2). The unadjusted difference-in-differences analysis showed that, the mean number of days of medicine procurement had decreased marginally (around 0.7 days = 16 hours) while there was a decrease of 26 rupees in out-pocket-expenditure on NCD medicines. Similarly, an overall 1.8% increase in patients visiting to PHC for NCD medication was found. However, these changes were not statistically significant. After adjusting for co-variates, the amount and direction of change in effectiveness remained the same and were statistically not significant (Table 2).

Role of predictors on determining reach and effectiveness of the intervention

Taluka was found to be a significant predictor across all outcomes. The differences in health system performance at the taluka level could have influenced the reach and effectiveness of the intervention in different ways; other socio-economic and taluka-specific factors could also explain this. We found age to be a
significant predictor for the mean number of days of availability of key NCD medicines at home. Older patients tend to procure NCD medicines for longer days. Occupation (those were employed tend to spend more and procure medicine for more days) was significantly associated with OOP on NCD medicines and mean number of days for medicine availability at home. We found education to be a significant predictor for OOP and source from which medicines were procured. With increase in education higher reliance on private facilities for medicines and incurring more OOP was evident. Type of disease and medicine source were significantly associated with OOP. Patients with diabetes spent more than patients with hypertension and patients with two or more NCDs spent more than patients with a single disease. Patients spent more at private facilities as expected. Time taken to reach PHCs significantly associated with the number of days of availability of medicines with NCD patients. Those taking more time to reach a particular facility did tend to procure for more days of medicines. More than effect of increased access to PHCs, improved paying capacity reflected on reduced catastrophic health expenditure across arms from baseline to end-line. However, difference across study arms was not significant (Table 3).

Other predictors/factors that played role in reach and effectiveness of the intervention

Episodic availability of NCD medicines and logistics

Although overall stock-out of medicines decreased from baseline to end-line, medicines stock particularly those for diabetes and hypertension remained episodic across PHCs of all study arms during greater part of the intervention period. This happened despite availability of stocks at the district level most of the times. In many PHCs, this appeared to be due to higher priority given to antibiotics during medicines indent process. The availability of laboratory supplies such as glucometer strips was also poor in most of the PHC laboratories.

Outside prescription of medicines at PHCs

From our household survey we found that although nearly half of the NCD patients visited PHCs during our intervention period only 11% of them had obtained medicine from these PHCs anytime ever during this period. Although the number of patients seeking NCD care and medicines at PHCs improved, it still remained low. Most patients purchased medicines from private pharmacies near PHCs through prescriptions provided by the PHC doctors.

Acceptability of awareness material and patient record books

Awareness material on common NCDs including posters on diet control and lifestyle modification were appreciated widely by health workers and were well utilised. PHC doctors reported positive feedback on acceptability of patient-retained health cards for diabetes and hypertension.

Challenges of record maintenance

In the busy healthcare establishments (all three taluka hospitals and some of the busy PHCs), maintenance of the NCD patient records, NCD follow-up patient registers was challenging. In most PHCs pharmacists and laboratory technicians maintained these records. In less than 40% of intervention PHCs (n = 26) at least 75% of patient record books had been issued to patients. Despite challenges in busy PHCs, 96% of PHCs maintained the NCD register. In only six PHCs, this register had not been maintained for three consecutive months.

NCD agenda in ARS meetings

Despite widespread policy level focus on NCDs, ARS committees rarely discussed NCDs; nor did they fulfil stock-outs (if any) of NCD medicines from budgets available to them. In only nine PHCs (of the 13 intervention PHCs), there was at least one discussion on NCD care at the PHC during an ARS meeting in the intervention period.

Human resource shortages at PHCs

This was one of the key issues observed in the study PHCs. In many PHCs either the doctor or the other staff (laboratory technician, pharmacist, nurse-midwife) were either part-time (due to being in charge of multiple facilities at once due to shortages elsewhere) or unavailable. Many patients missed follow-up visits in PHCs where doctor was not available regularly. At one of the study talukas almost half of all the PHCs were running without a doctor. There was no doctor in six PHCs and no pharmacist in seven PHCs out of all the 39 study PHCs during our last follow up visit. Of the 39 study PHCs, only in 14 PHCs was the doctor available for more than 10 consecutive months, and in 23 PHCs the pharmacist was available for more than 10 consecutive months.

Gaps in essential diagnostics to provide NCD care

Amongst the 13 arm-A PHCs, 12 had a functional pharmacy and eight had a functional laboratory. Out of these eight laboratories, only six could test blood glucose. In the 13 arm-B PHCs, 10 had functional pharmacies and all had functional laboratories. However, two of the PHCs did not have facility for testing blood glucose levels. In the 13 control PHCs, all had functional pharmacy, nine had functional laboratory out of which three did not have facility to test blood glucose.

Discussion

The aim of this study was to understand if (and how) interventions aimed at health service optimization alone or combined with community platform strengthening improve the access to medicines at the primary health care level, within the context of a local health system. We found that arm-B that received both the interventions fared marginally better than the other two arms in terms of key intervention outcomes such as medicine availability at home and at PHCs, however, the difference was not statistically significant. The paying capacity of the study population improved during the two-year period, as evident by the decrease in proportion of patients borrowing money or selling assets to purchase medicines and increased household income levels. This could also be
associated the increase in proportion of patients obtaining medicines from PHCs. However, since the number of participants receiving free medicines from PHCs remained relatively low and similar across study arms, it could more likely mean that increased affordability may be due to an overall increase in median household income, which nearly doubled across all the three arms. Increased income has been often used to finance healthcare expenditure(34).

One of the key components of both the interventions arms was capacity building of the PHC staff in management of NCDs at the primary health care level. The uptake of such a capacity building exercise and its sustainability is influenced by several factors. Bates et al (35) found that it took on an average 66 months for a capacity building project to become sustainable in terms improved knowledge and effectiveness. Since follow-up survey in our study was conducted just a year and half after the capacity building exercise, it is probably too early to assess the result of the intervention such as this. In addition, the connection between capacity building and performance is not straightforward; earlier studies in the district in relation to capacity building have shown the complex relationship between capacity-building and various organizational and individual factors(36). Bates et al (35) also identified some of the challenges that influence the performance following capacity building, such as high staff turnover, issues with adoption of new activities into existing systems, and influencing policy development. These were very similar to what we found in our study. In only 40% of the PHCs the doctor and 55% of PHCs the pharmacists, at follow-up survey, were available for ten months consecutively in the same PHC. This is reflected in the fact that only nearly 50% of the doctors and pharmacists received both the capacity building trainings.

We found that the intervention effects were not uniform within the intervention groups. Some PHCs were able to overcome health system barriers better than the others due to strong motivation and leadership of their staff and due to good rapport with the local community participation platforms. In some cases, even with motivated staff, contextual issues such as episodic medicines supplies, frequent staff turnovers affected the implementation of the intervention. The PHCs being part of a larger complex health system were influenced by challenges that were beyond control of study interventions to address.

In addition, substantial gaps in the governance at the district and state level influenced better access to medicines to patients. While, on one hand, decision space available at the district level to influence better availability of medicines at the PHC level was limited, on the other hand, the state level drug supply agency was not adequately responsive to the needs of PHCs. Even in terms of prioritizing NCDs within the primary health context, the NPCDCS programme fails to provide substantial resources to the PHC/sub-centre in order to make a difference in NCD care at this level. The role of PHC is limited to screening, case identification and referral to higher centers. This also is a likely influence on the lack of priority given by the PHC staff to NCD medicines while indenting and also the provision of care at the health centers.

An important societal/health system factor that influences public services utilisation is the trust in the PHC/public system itself. In this study, we have earlier reported the influence of trust in medicines and in public services as possible drivers of private sector dependence for NCD care among rural populations in Tumkur. Perceptions of both the healthcare providers as well as the patients about medicines at PHCs exerted an influence on utilisation of PHCs. A lack of trust in the quality of government medicines that was prevalent among health workers (both public and private) and patients could influence reach and effectiveness of health services interventions. Despite objective tests revealing comparable quality of medicines between government and private sector, subjective perceptions of medicine quality in fact deteriorated from baseline to follow-up. This also could explain poor preference to PHC medicines by NCD patients despite improvements in their availability; it also explains possible reliance on outside prescriptions of medicines by PHC health workers.

**Conclusion**

Our study reinforces the fact that access to medicines is embedded within a complex adaptive health system and its barriers are therefore equally complex and influenced by factors at multiple levels of the system(37). Interventions to improve access to medicines in district and local health systems such as in the southern Indian district (Tumkur) presented in this paper need to address wider societal and health system factors such as trust in public services and ensure stability and capacity of human resources within the public services, if they have to succeed. Although findings from this study is limited to the study geography, inferences and insights could be generalized for such similar settings.

**Limitations**

Since our intervention targeted the health services the unit of randomization and intervention was at the PHC level and not at individual patients. Feasibility also constrained our sample size. Yet another challenge in the analysis and reporting results from field experimental studies like ours (cluster randomised trial) is working within health services implies an acceptance of lack of control over diffusion of the intervention in part or full to control arms. Indeed, our overall advocacy to improve medicines supply for NCDs at the district and state level covered all PHCs as it would have been neither feasible, nor ethical to restrict such advocacy to the intervention PHCs only. Although, we conducted an intention to treat analysis, in the complex health services settings such as ours, it is not possible to carefully separate the effects of particular package of interventions on specific PHCs.

**Abbreviations**

ARS: Arogya Raksha Samiti  
NPCDCS: National Programme for Prevention and Control of Cancer, Diabetes, Cardiovascular Diseases & Stroke  
NCDs: Non-communicable diseases  
OOP: Out-of-pocket (OOP) health expenditure  
PHCs: Primary health centres
**Declarations**

**Trial Registration**

Trial registration number CTRI/2015/03/005640. This trial was registered in the Clinical Trial Registry of India (CTRI) after the PHCs were enrolled in the study (retrospectively enrolled). The CTRI is the nodal agency of Indian Council of Medical Research for registration of all clinical, experimental, field intervention and observation studies.

**Adherence to CONSORT Guidelines**

This study adheres to the CONSORT reporting guidelines and the CONSORT checklist has been provided (Supplementary material 4).

**Ethics approval and consent to participate**

Ethics approval was obtained from WHO Ethics Review Committee and the Institutional Ethics Committee of the Institute of Public Health (IPH), Bangalore. Written Informed consent had been obtained from study participants.

**Consent for publication**

Informed written consent was obtained from each of the participant during the data collection process.

**Availability of data and materials**

The datasets generated and/or analysed during the current study are available in the Figshare repository in an anonymised form: [https://figshare.com/articles/dataset/Dataset_of_the_ATM_study_implemented_in_southern_Kamataka_primary_health_centres_to_improve_access_to_medici communicable_diseases/12957185](https://figshare.com/articles/dataset/Dataset_of_the_ATM_study_implemented_in_southern_Kamataka_primary_health_centres_to_improve_access_to_medici communicable_diseases/12957185)

**Competing interests**

None declared

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**Authors’ contributions**

MKP and PNS were involved in the conception and design of the study. Data collection, management and analysis were implemented by MKP and supported by MAE and PNS. UB supervised the final stages of the analysis and reporting. MKP wrote the first draft of the manuscript and all authors reviewed and contributed to the writing. All authors contributed to interpretation of findings and preparing, reading, revising and approving the manuscript.

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Tables

Due to technical limitations, table 1 and 2.xlsx are only available as a download in the Supplemental Files section.

Table 3: Out-of-pocket expenditure on NCD medicines

|                          | Baseline          | Endline           |
|--------------------------|-------------------|-------------------|
|                          | A (N=404)         | B (N=397)         | Control (N=353) | A (N=447) | B (N=413) | Control (N=392) |
| Median OOP in Indian Rupees | 130               | 90                | 135              | 160       | 130       | 170             |
| ≥20% Household income on NCD medications | 16.9%             | 8.1%              | 11.7%            | 5%        | 3.2%      | 4%              |