Availability, Sales, and Affordability of Tobacco Cessation Medicines in Kerala, India

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Abstract

Background—India is the world's second largest consumer of tobacco, but tobacco cessation remains uncommon due, at least in part, to underutilization of cessation pharmacotherapy. We evaluated the availability, sales, and affordability of nicotine replacement therapy, bupropion and varenicline in the south Indian state of Kerala to understand potential reasons for underutilization.

Methods and Results—From November 2016 to April 2017, we collected data on availability, inventory and pricing of cessation medication through a cross-sectional survey of 199 public, semi-private (Karunya), and private pharmacies across five districts in Kerala using World Health Organization/Health Action International methodology. Revenue and sales data were obtained from the latest Pharmatrac medication database. We assessed affordability using individual and household-level income and expenditure data collected from November 2014 to November 2016 through the Acute Coronary Syndrome Quality Improvement in Kerala randomized trial. Cessation medications were not available in public hospitals (0%, n=58) nor in public specialty centers (0%, n=10) including those designated to provide cessation services. At least one cessation medicine was available at 63% of private pharmacies (n=109) and 27% of Karunya (semi-private) pharmacies (n=22). Among the 75 pharmacies that stocked cessation medications, 96% had

nicotine replacement therapy, 28% had bupropion, and 1% had varenicline. No outlets had sufficient inventory for a patient to purchase a 12-week treatment regimen. There were an estimated 253,270 treatment regimens sold throughout India and 14,092 in Kerala in 2013–2014. Treatment regimens cost 1.9 to 13.0 times the median amount spent on smoked tobacco and between 8% to 52% of non-subsistence income.

Conclusions—Tobacco cessation medications are unavailable in the Kerala public sector and have limited availability in the private and semi-private sectors. When available, medications are unaffordable for most patients. Addition of tobacco cessation medication onto national and state essential medicines lists may help increase access.

India is the world's second largest consumer of tobacco.[1] There are 100 million smokers in the country and an estimated 1 million smoking-related deaths each year.[2,3] While 38% of Indian smokers make a quit attempt each year, few succeed.[4] India has a quit ratio of 13% (defined as former daily smokers among ever daily smokers), compared to over 50% in the United States.[4,5] If India's annual quit rate were estimated to be 5%, then the routine use of tobacco cessation pharmacotherapy would increase this quit rate to as high as 11%.[6] However, there is substantial heterogeneity in quit rates across different states in India.[4]

A major reason for overall low quit rates in India is underutilization of pharmacotherapy for tobacco cessation; only 4% of Indian smokers use medicines during a quit attempt despite high-quality evidence demonstrating their effectiveness.[4] A 2013 Cochrane overview and meta-analysis compared the tobacco cessation medications to placebo in 267 studies involving 101,804 participants and found high quality evidence supporting the use of nicotine replacement therapy (RR 1.60; 95% CI 1.53 to 1.68), bupropion (RR 1.69; 95% CI 1.53 to 1.85), and varenicline (RR 2.27; 95% CI 2.02 to 2.55) for cessation.[7]

In 2004, India became a party to the World Health Organization's Framework Convention for Tobacco Control (FCTC). Article 14 of the FCTC recommends that countries improve access to pharmaceutical treatment of tobacco dependence in an effort to improve quit rates.[8] The United Nations General Assembly's Political Declaration on Noncommunicable Diseases in 2011 and the World Health Organization's Global Action Plan in 2013 call for countries to achieve 80% availability of essential medicines in both public and private pharmacies to treat noncommunicable diseases by 2025, and this aim includes nicotine replacement therapy (NRT).[9,10]

In 2015, India's National Tobacco Control Programme introduced a funding infrastructure to establish cessation counseling centers in each district with an annual budget of 200,000 Indian rupees (US dollars 3,155) per district to provide cessation pharmacotherapy.[11] These investments notwithstanding, data are limited on the availability and affordability of pharmacotherapy for tobacco cessation, including in states with relatively high quit rates such as Kerala, which has a quit ratio of 33%.[4] We sought to fill this gap by evaluating the availability, sales, and affordability of medicines for tobacco cessation in Kerala through a cross-sectional survey of pharmacies with linked sales and income data. Kerala is considered one of the highest-performing states based on health and development indices. It has the highest life expectancy (77 years vs. 68 years nationally), literacy rate (94% vs. 74%), and human development index in India.[12–14] If Kerala is found to have low availability of

medicines for tobacco cessation, then there will likely be even lower availability in other states with relatively lower performances on health and development metrics.

Methods

Cross-sectional survey to determine medicine availability and pricing

We performed a cross-sectional field survey on medicines availability and pricing between November 2016 and April 2017 using methods recommended by the World Health Organization and Health Action International.[15] We used the Pharmatrac database to identify effective cessation medicines that had non-zero sales in Kerala and included these on the survey form: nicotine replacement therapy (NRT), bupropion, and varenicline. A single data collector (SS) invited pharmacists, medical superintendents, or prescribing providers at each institution to respond to surveys. The questionnaire helped assess medicines availability, inventory, and pricing. A drug was considered available if it was in stock on the day of survey.[15] The median discount offered in private pharmacies was calculated through comparison of sales price at each pharmacy to the maximum retail price for each medication. Per capita estimates for medicines availability were derived using the 2011 census of India and the 2010 Global Adult Tobacco Survey.[4,16]

We conducted surveys in 5 out of 14 districts in Kerala which were purposively sampled: Trivandrum, the state capital; Ernakulam, the major urban center; Kozhikode, the district targeted by the National Tobacco Control Programme; Kollam, a suburban district; and Wayanad, a rural district. These districts represent a wide geographic and socioeconomic distribution and cover rural-urban and north-south gradients in the state.

We used the Kerala Directorate of Health Services (DHS) list of modern medicine institutions to select public hospitals in each district.[17] We sampled all general and district hospitals as well as two randomly selected health facilities from sequentially lower levels of care: taluk hospital, tuberculosis/chest hospital, community health center, 24/7 primary health center, and primary health center. Patients receive preventive and general medical care at primary health centers (PHCs) and community health centers, inpatient care or procedural evaluation at taluk hospitals, and tertiary care services in district and general hospitals. At each selected hospital, we surveyed the public pharmacy on site and two private pharmacies located in close proximity to the institution per the World Health Organization/Health Action International methodology.[15] The rationale was that patients who visited these public hospitals may opt to fill their prescription at a nearby private pharmacy if there was no availability on site. We only included private pharmacies that were listed on the State Drugs Controller Office's list of registered medical outlets to qualify for inclusion.[18]

We also included a convenience sample of public specialty centers that provide de-addiction services, including mental health centers, medical colleges, and the Regional Cancer Centre, which hosts the only World Health Organization-affiliated tobacco cessation clinic in Kerala. Doctors at the primary care levels may refer patients to these locations to avail cessation pharmacotherapy under the assumption that it would be available in the pharmacy's formulary. Lastly, we included a convenience sample of Karunya (semi-private) community

pharmacies, a for-profit chain of pharmacies run by the Kerala Medical Services Corporation Limited.

Kerala Medical Services Corporation Limited is a government-owned drug procurement agency that is responsible for the procurement and distribution of drugs to public health centers and Karunya community pharmacies in Kerala. Kerala Medical Services Corporation Limited utilizes the tender (bidding) process to negotiate prices with major drug manufacturers and obtain medicines at bulk discounts. Generic medicines on the state essential medicines list are stocked at public sector pharmacies and distributed to patients free of cost, whereas branded medicines are sold through Karunya outlets. Medicines purchased for this purpose are first stored in Karunya depots and subsequently brought to Karunya points-of-sale on an as-needed basis, where patients can buy them at discounts ranging from 20% or more when compared to other retail outlets.[19]

De-identified data and analytic code from this cross-sectional survey will be made publicly available at the time of publication on GitHub. Data will be available indefinitely at: https://github.com/smitha48f/Tobacco-Meds-Kerala-2017.[20]

Sales of cessation pharmacotherapy in Kerala and India

We obtained data on medicine name, unit price, units sold, and total sales in India and Kerala for all tobacco cessation medications from the Pharmatrac database for the fiscal year that spanned from March 2013 to February 2014.[21] Pharmatrac is operated by AIOCD Pharmasofttech AWACS Pvt. Ltd., a pharmaceutical market research company. The dataset provides monthly pack-wise information on medicine sales (values and volumes) as well as prices (maximum retail price, price to retailer and price to stockist). The data are collected from a sample of 18,000 stockists across 23 regions in India and are projected to reflect the overall sales in the private sector in the different regions as well as the country as a whole. We calculated sales, market share and units sold for each medicine (NRT, bupropion, and varenicline). We estimated treatment regimens for each medicine sold per capita using the recommended course of medication (12 weeks), number of tablets or gums required for each medication formulation (see Supplemental Table 1), population size from the 2011 census of India and smoking prevalence rates from the 2010 and 2017 editions of the Global Adult Tobacco Survey.[3,4,16]

Microeconomic data to measure affordability

To assess affordability of medications, we compared the cost of cessation pharmacotherapy, as determined by our field survey, to non-subsistence income and expenditure on tobacco products, all over a 12-week period. We derived individual- and household-level income and expenditure data from microeconomic surveys administered to a sub-sample of 1,716 respondents who had been hospitalized for acute coronary syndrome and enrolled in the Acute Coronary Syndrome Quality Improvement in Kerala (ACS QUIK) cluster-randomized, stepped wedge clinical trial between November 2014 and July 2016 (clinicaltrials.gov: NCT02256657).[22] The survey utilized a previously published instrument developed in conjunction with the World Bank to estimate individual- and household-level

costs associated with cardiovascular disease hospitalization.[23] Subsistence expenditures were defined as expenditures for food, rent, gas, education, transport, and insurance.

Statistical analysis

We report medicines availability as sample proportions. We compared availability by sector, level of care and district, and tested for differences through logistic regression. We summarized medicine inventories with median and 25th and 75th percentiles and medication price as maximum retail price in the private sector and Karunya retail price for the Karunya pharmacies. We calculated total cost for recommended treatment regimens over 12 weeks using the average price per unit of medicine in each sector (see Supplemental Table 1 for details on treatment regimens). We used the International Monetary Fund exchange rate applicable at the time of data collection for conversion of all pricing data.

For data from ACS QUIK, we summarized household income and expenditure data with median and 25th and 75th percentiles. We evaluated economic differences between tobacco users at baseline, tobacco users at 30 days after an ACS event, and by tobacco type using Mann-Whitney U or Kruskal-Wallis tests. We analyzed data using SAS v9.4 (Cary, NC).

Ethics board

We sought and received ethics board approval for this study from the Sree Chitra Tirunal Institute of Medical Sciences and Technology, Centre for Chronic Disease Control, Vanderbilt University, and Northwestern University. In accordance with our ethics board approval, we sought and received oral consent from all survey respondents. No pharmacies refused to participate.

Results

Medicine availability and pricing

We surveyed 199 pharmacies, including 58 pharmacies in public hospitals, 10 pharmacies in public specialty centers, 109 private pharmacies near the public hospitals, and 22 Karunya community pharmacies.

Cessation medications (NRT, bupropion, or varenicline) were available in none of the 58 public hospitals and none of the 10 public specialty centers that were surveyed (Table 1). The surveyed specialty centers included locations where tobacco cessation services were to be provided: government mental health centers in Kerala (n=3), the Regional Cancer Centre which houses the state's official tobacco cessation clinic, two medical colleges with de-addiction units, the State Tuberculosis Cell, two women and children's hospitals, and the major tertiary care center for heart attack and stroke management. Public hospitals and specialty centers were not included in any further analysis.

Among surveyed private pharmacies (n=109), at least one cessation medicine was available at 69 (63%) facilities. The private pharmacies located close to general hospitals had the greatest availability (83%) and those located near primary health centers had the least (51%). Among surveyed Karunya community pharmacies (n=22), at least one cessation medicine was available at 6 (27%) facilities. We surveyed one-third of the Karunya points-of-sale

(n=18) and found cessation medicine was available at 3 (17%). We surveyed all Karunya depots (n=4) and found at least one cessation medicine was available at 3 (75%). A cessation medication was 4.6 (95% CI 1.7 – 12.7) times more likely to have been available at a private pharmacy compared to Karunya points-of-sale and depots.

Table 2 demonstrates cessation medicine availability by district. Kozhikode had the highest availability (85% of private centers and 40% of Karunya), and Wayanad had the lowest availability (50% of private centers and 0% of Karunya). Cessation medication was 3.9 (95% CI: 1.1 – 13.8) times more likely to be available in Kozhikode among private and Karunya centers compared to Wayanad. We found no difference in availability between Ernakulum, Kollam, Trivandrum and Wayanad.

NRT (sold as Nicogum or Nicotex by Cipla Limited) was carried by the majority (96%, n=72) of private and Karunya pharmacies that carried cessation medications (Supplemental Table 2). Nicotex (95%, n=71) was carried more often than Nicogum (20%, n=15). Bupropion (sold as Bupron by Sun Pharmaceuticals Limited) was carried by 21 (28%) pharmacies; a similar number of pharmacies carried Bupron SR (19%, n=14) or Bupron XL (21%, n=16). Varenicline (sold as Champix by Pfizer) was carried by only one (1%) pharmacy, a Karunya Depot located on a medical college campus.

Private pharmacies either sold medications at the maximum retail price (n=89 out of 109 private pharmacies) or with a small discount (n=20, median discount 9%, interquartile range 6% to 10%). When a pharmacy stocked NRT, the median inventory was 36 gums (interquartile range: 18 – 90) for the 2 mg dose and 30 gums (interquartile range: 18 – 90) for the 4 mg dose. A 12-week treatment regimen of NRT requires 504 gums. Pharmacies on average carried 11% of the amount required by a single patient. Similarly, pharmacies that stocked bupropion had a median inventory of 34 tablets (interquartile range: 30 – 90) for the 150 mg dose and 60 tablets (interquartile range: 40 – 158) for the 300 mg dose, or an average of 24% of the amount required by a single patient. No outlets had sufficient inventory for a 12-week course of NRT or bupropion.

Medications were sold at a 20% to 25% discount from maximum retail price in the Karunya pharmacies (Table 3). The 12-week regimen of bupropion had the lowest price, costing between INR 730 – 1,535 (USD 11 – 24) based on dose and location. NRT gums (INR 2,464 – 3,864; USD 38 – 59) and varenicline (INR 7,789 – 10,016; USD 120 – 154) were considerably more expensive. However, NRT had the lowest pack price (INR 44 – 59; USD 0.68 – 0.91).

Sales of cessation pharmacotherapy in Kerala and India

There were 253,270 treatment regimens reportedly sold throughout India and 14,092 in Kerala between March 2013 to February 2014 (Table 4). Two-thirds of national sales (65%) were from NRT gums, 31% from bupropion, and 4% from varenicline for a total revenue of USD 7.7 million. Most (70%) of Kerala's sales were from NRT gums, 21% were from bupropion and 9% were from varenicline for a total revenue of USD 371,652. Based on the Global Adult Tobacco Survey, there are 100 million current smokers in India (GATS 2017) and 3.4 million current smokers in Kerala (GATS 2010; state level estimates from GATS

2017 are pending).[4,3] Therefore, we estimate that 0.3% of the current smokers in India (1 regimen per 395 users) and 0.4% in Kerala (1 regimen per 243 users) could complete a regimen of cessation pharmacotherapy in a given year based on smoking prevalence and cessation medication sales data.

Affordability of cessation pharmacotherapy: Microeconomic data from ACS QUIK

There were 1716 (74% [n=1262] male) participants in the ACS QUIK microeconomic study (Table 5). Two out of every five (38%; n=479) of men reported recent tobacco use within the past 1 year at the time of hospitalization for ACS, and the majority (90%; n=430) of these men reported exclusive use of smoked forms of tobacco such as cigarette or bidi. A minority of men reported exclusive use of smokeless tobacco (7%; n=34) and a few used both forms concurrently (3%; n=15). Few women (3% of women surveyed; n=15) reported recent tobacco use, including a similar proportion of smokers (53%; n=8) and smokeless tobacco users (47%; n=7). At the 30-day microeconomic assessment, of the 494 recent tobacco users, only 12 (2%) reported continued use.

We assessed the non-subsistence household income and household expenditure on tobacco products to compare the relative affordability of cessation pharmacotherapy in present-day Kerala. Median monthly non-subsistence household income for tobacco users prior to heart attack was INR 5,000 (interquartile range: 1,600 – 9,000) per month, or INR 15,000 over a 12-week period. Among tobacco users at baseline enrollment, participants reported spending INR 150 (interquartile range: 0 – 300) on tobacco per month, or INR 450 in a 12-week period (Table 6). Participants who only used smoked products spent INR 200 (interquartile range: 0 – 300) per month, or INR 600 in a 12-week period. Tobacco users had lower household monthly income before and after their ACS event compared with those who did not use tobacco, and the former also had higher household monthly expenses. There was no difference in household monthly income and expenditures between tobacco users who quit tobacco before 30-day follow up and those who did not. Those who continued to use tobacco at 30-days reported higher monthly expenditure on tobacco products at enrollment.

The Karunya price for a full treatment regimen of NRT 2 mg was INR 2,464, which is 4.1 times the median amount spent on smoked tobacco products over a 12-week period, or 16% of 12-week non-subsistence household income. Karunya-priced bupropion (300 mg XL formulation) and varenicline cost 1.9 and 13.0 times the median amount spent on smoked tobacco and were equivalent to 8% and 52% of household non-subsistence income, respectively.

Discussion

Summary of results

Availability—Cessation medicines were not available in any public sector hospital in Kerala that was surveyed, including centers that provide tobacco cessation counseling or mental health services. Public hospitals have the option to locally procure medications that are not supplied to them by Kerala Medical Services Corporation Limited. However, no such procurement took place in the sites surveyed. Possible explanations for the absence of local

procurement include financial constraints, procedural limitations, and low demand for these medications from patients and doctors. The National Tobacco Control Programme has allocated 200,000 INR per district for purchase of cessation medications annually, but this survey found limited evidence of implementation.[11] Utilization of these funds is a key step towards increasing availability.

Medication availability was much higher, but still suboptimal, in the private sector. Two-thirds of private pharmacies had at least one cessation medication available. There was greater availability near general hospitals, which are located in major urban centers, and less availability near primary care centers, which are distributed in the rural and suburban areas. Karunya outlets had high availability in the depots (75%) but low availability in the points-of-sale (17%). Pharmacists at private and Karunya pharmacies reported low prescription rates by medical providers as the primary reason for not stocking the medications.

Sales—We found that sales of cessation pharmacotherapy were minimal in India and Kerala. The Global Adult Tobacco Survey (GATS) 2010 reported that 4.1% of current smokers in India and 1.1% in Kerala use pharmacotherapy during a quit attempt in a given year.[4] Our study found even smaller numbers when looking at sales of treatment regimens from the Pharmatrac database, with 0.3% of current smokers in India and 0.4% in Kerala completing a full regimen of pharmacotherapy each year.

Affordability—A 12-week regimen of bupropion (300 mg XL formulation) bought from a Karunya community pharmacy is the most affordable option for patients. A regimen of NRT gum is considerably more expensive than bupropion; however, because NRT has the lowest pack price, it is more affordable to patients with limited non-subsistence income and its sales reflect this. Varenicline has the highest cost per regimen, making the most effective drug cost prohibitive. Measures to make cessation pharmacotherapy more affordable may increase patient utilization.

Comparison with other studies

Previous studies have investigated the availability and affordability of essential medicines and medicines for cardiovascular disease prevention in India, but there are limited data for cessation pharmacotherapy. Despite having a robust generic pharmaceutical industry, India still experiences low rates of essential medicine availability: only 36% of a basket of 15 generic medicines were found in public outlets in India compared to 76% in private outlets.[24] Kerala may have somewhat higher medicines availability in the public sector compared to other parts of the country, but here too, availability remains low. A 2014 study conducted in nine public hospitals in Kerala found that an average of 58% of prescribed drugs presented for dispensing were actually dispensed (n=400 prescriptions).[25] A 2009 review on essential medicines found that India had the lowest public sector procurement prices compared to 35 other developing and middle-income countries, with median price ratios between 0.27 to 0.78 of the international reference price.[24] Despite the low procurement costs, medicines remained unaffordable. Inhalers and antibiotics sold in the public sector in Delhi cost 1.4 and 2.3 days' wages respectively for the lowest paid government workers in 2013.[26] The combination of aspirin, β blockers, angiotensin-

converting enzyme inhibitors, and statins was affordable to only 41% of Indian households in the Prospective Urban Rural Epidemiology study (n=16,874 households) based on a 20% capacity to pay threshold.[27] Our survey demonstrates that tobacco cessation medicines have even lower availability and affordability for most people who need them.

Experience in the United Kingdom suggests that utilization of cessation pharmacotherapy is influenced by reimbursement schemes. The United Kingdom made tobacco cessation medications available for reimbursement through the National Health Service in a phased manner starting in 1999. This change more than doubled the proportion of smokers using medicines during a quit attempt from 25% in 1999 to 61% in 2002.[28] Public sector distribution of tobacco cessation medications may increase utilization in Kerala as well.

Policy recommendations

The preliminary findings of the 2017 Global Adult Tobacco Survey in India demonstrate a decline in tobacco use prevalence from 275 million in 2010 to 267 million in 2017 (state level estimates have not yet been reported).[3] Reductions thus far have been attributed to a nationwide gutka ban, prohibition of sales of loose cigarettes, and the introduction of an 85% pictorial warning on tobacco packets. Recent initiatives to improve cessation rates have included: 1) introduction of a national quit line based at the Vallabhbhai Patel Chest Institute, which provides counseling to Hindi- and English speaking individuals; 2) launch of a mobile phone messaging service to promote cessation operated by the National Health Portal of India; and 3) publication and implementation of national treatment guidelines.[29] Organizations such as the Voluntary Health Association of India (VHAI), Quit Tobacco International and Health Related Information Dissemination Amongst Youth – Student Health Action Network (HRIDAY-SHAN) also engage in media and education initiatives to promote tobacco cessation. The Indian government aims to achieve a 30% relative reduction in tobacco use prevalence by 2025.[3] Improved access to cessation pharmacotherapy, including reaching the 80% availability target in public and private pharmacies, will help tobacco users in India quit to help achieve these ambitious goals.

We contend that the inclusion of tobacco cessation medications on both India's national and state essential medicines lists is a key step to improving availability and affordability of cessation pharmacotherapy. In India, the national essential medicines list is the basis for price regulation in the private sector according to current policy whereas the state essential medicines list is the basis for public sector procurement for different state governments.[30] Within Kerala, inclusion of cessation medicines on the state essential medicines list would allow Kerala Medical Services Corporation Limited to procure these medicines for public sector distribution through its streamlined tender and bulk purchasing practices.

On a global level, medicines included on the World Health Organization's Model List of Essential medicines are more likely to be available than medicines not on the Model List. Data from 23 countries demonstrate that medicines on the Model List have a mean availability of 62% compared with a mean availability of 27% among those medicines not on the Model List based on a similar methodology.[31] A 2010 study in sub-Saharan Africa found that antihypertensive medicines included on national essential medicines lists were more affordable than those not included, highlighting the importance of the national list in

securing financial accessibility.[32] The World Health Organization added nicotine replacement therapy to its model list of essential medicines in 2009, and this publicly available application could be adapted to facilitate incorporation into national and state-level essential medicines lists.[33]

While it is beyond the scope of this study, we recognize that policies to improve utilization of cessation pharmacotherapy must also increase demand. We postulate that demand for pharmacotherapy may be enhanced through policies that target physician confidence in the prescription of pharmacotherapy and patient awareness of these treatments. This may be achieved through expansion of medical education curricula to include evidence-based approaches to tobacco cessation, dissemination of standard treatment guidelines, and promotion of pharmacotherapy in government-based media campaigns. As India expands its health insurance schemes, economic policies to promote cessation will also have increasing relevance.

Strengths and limitations

Our study has several strengths. First, ours is the first contemporary, published evaluation of tobacco cessation pharmacotherapy availability, sales, and affordability in Kerala and in India. Second, we used structured survey methods recommended by the World Health Organization and Health Action International for capturing valid data on availability and price. Third, we surveyed all tertiary care centers in the five selected districts along with a large proportion of secondary and primary care centers, which improves our generalizability of results. Lastly, we leveraged existing data on sales and affordability to place our results into context for patients, doctors, manufacturers, and policymakers in Kerala.

Nevertheless, our study also has limitations. First, our sampling frame was not random nor did we sample around private hospitals based on the World Health Organization/Health Action International methodology. Thus, we may have over- or underestimated availability or price. Nevertheless, our finding that no public pharmacies carried tobacco cessation pharmacotherapy is striking. Also, the availability of tobacco cessation pharmacotherapy in private pharmacies is below the World Health Organization 25×25 target (80%).[10] Second, we limited our data collection on availability and affordability to the state of Kerala. Our findings may not be generalizable to India as a whole or to other individual states given substantial geographical variability with respect to health system performance and health-seeking behavior. However, we expect availability and affordability to be even lower in other states in India with lower quit ratios and lower incomes. Third, we collected income and expenditure data from individuals who have survived acute myocardial infarction, which may bias our results to those who access acute medical services. Comparison of our cohort's expenditure data to GATS 2010 suggests that we may have underestimated monthly expenditure on tobacco use.[4] The forthcoming, complete GATS 2017 report will further help place our results in clearer context. Lastly, we used the Pharmatrac database of sales data, which, unlike prescription data, does not provide individual level information regarding the diagnosis for which the medicines were prescribed or the treatment regimen prescribed, limiting our ability to interpret the results. Sales data, however, have certain merits over prescription data because they capture over-the-counter sales, which are common in India.

Despite the aforementioned limitations, our data demonstrate that cessation pharmacotherapy has limited availability and affordability in Kerala.

Conclusions

Tobacco cessation can help the average tobacco user regain between 6 to 10 years of life and can help patients with ischemic heart disease reduce the risk of mortality by one-third (36%).[34,35] Our study highlights important gaps in access to cessation pharmacotherapy, a crucial component of tobacco control and cardiovascular risk reduction. We found that NRT, bupropion, and varenicline are unavailable in the public sector in Kerala and have limited availability in the private and semi-private sectors. NRT gums have the highest sales both in Kerala and India, possibly because of low pack prices, whereas bupropion remains the more effective and affordable option when looking at the full treatment regimen. Varenicline, the most effective medication, is the least available and most expensive. Cessation medicines are underutilized in Kerala and in India, with less than 1% of current smokers completing a treatment regimen each year. Future studies should investigate reasons for the low adoption of pharmacotherapy. Assessment of provider knowledge, prescription practices, patient opinions on treatment acceptability, and patient adherence to treatment may be useful.[36] Policies for tobacco control and cardiovascular risk reduction in India should incorporate measures that promote tobacco cessation. Introduction of cessation pharmacotherapy into the state and national essential medicines lists would be an important next step.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

Appendix

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References

1. Reddy, KS., Gupta, PC. Tobacco control in India. Ministry of Health and Family Welfare, Government of India; 2004. Available at: http://www.who.int/fctc/reporting/Annex6_Report_on_Tobacco_Control_in_India_2004.pdf?ua=1. Accessed 27 September 2017

2. Jha P, Jacob B, Gajalakshmi V, Gupta PC, Dhingra N, Kumar R, Sinha DN, Dikshit RP, Parida DK, Kamadod R, Boreham J, Peto R, RGI-CGHR Investigators. A nationally representative case-control study of smoking and death in India. N Eng J Med. 2008; 358:1137–1147.

3. Chaturvedi, P., Sarin, A., Seth, S., Gupta, PC. India: steep decline in tobacco consumption in India reported in second Global Adult Tobacco Survey (GATS 2017). BMJ Blogs. Jun 23. 2017 Available at: http://blogs.bmj.com/tc/2017/06/23/india-steep-decline-in-tobacco-consumption-in-india-reported-in-second-global-adult-tobacco-survey-gats-2017/. Accessed 23 October 2017

4. International Institute for Population Sciences, Ministry of Health and Family Welfare, Government of India. Global Adult Tobacco Survey India report (GATS India). 2009–10. Available at: http://www.searo.who.int/tobacco/documents/2010-pub2.pdf?ua=1. Accessed 27 September 2017

5. US Department of Health and Human Services. The health consequences of smoking—50 years of progress: a report of the Surgeon General. US Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion. Office on Smoking and Health; 2014.

6. Mishra GA, Pimple SA, Shastri SS. An overview of the tobacco problem in India. Indian J Med Paediatr Oncol. 2012; 33:139–45. [PubMed: 23248419]

7. Cahill K, Stevens S, Perera R, Lancaster T. Pharmacological interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database Syst Rev. 2013; 328:CD009329.

8. World Health Organization. WHO Framework Convention on Tobacco Control. 2003. Available at: http://www.who.int/fctc/text_download/en/index.html. Accessed 27 September 2017

9. United Nations General Assembly. Political declaration of the high-level meeting of the general assembly on the prevention and control of non-communicable diseases. Available at: http://www.un.org/ga/search/view_doc.asp?symbol=A/66/L.1 Accessed 27 September 2017

10. World Health Organization (WHO). Global action plan for the prevention and control of noncommunicable diseases 2013–2020. 2013. Available at: http://apps.who.int/iris/bitstream/10665/94384/1/9789241506236_eng.pdf. Accessed 27 September 2017

11. National Tobacco Control Programme. Operational Guidelines. National Tobacco Control Cell, Ministry of Health and Family Welfare, Government of India; 2015. Available at: http://pbhealth.gov.in/Letter_tob%20.pdf. Accessed 27 September 2017

12. Office of the Registrar General and Census Commissioner of India. Sample registration survey based abridged life tables 2010 to 2014. Available at: http://www.censusindia.gov.in/Vital_Statistics/SRS_Life_Table/2.Analysis_2010-14.pdf. Accessed 27 September 2017

13. Government of India. Ranking of state and union territories by literacy rate. 2011. Available at: http://censusindia.gov.in/2011-prov-results/data_files/india/Final_PPT_2011_chapter6.pdf. Accessed 27 September 2017

14. Suryanarayana, MH., Agrawal, A., Prabhu, KS. Inequality adjusted human development index for India's states. United Nations Development Programme; New Delhi, India: 2011.

15. World Health Organization. Health Action International. Measuring medicine prices, availability, affordability and price components. 2008. Available at: http://apps.who.int/iris/bitstream/10665/70013/1/WHO_PSM_PAR_2008.3_eng.pdf. Accessed 27 September 2017

16. Office of the Registrar General and Census Commissioner, Ministry of Home Affairs, Government of India. Census of India. 2011. Available at: http://www.censusindia.gov.in/2011-prov-results/prov_data_products_kerala_.html. Accessed 27 September 2017

17. Directorate of Health Services, Government of Kerala. List of modern medical institutions under Directorate of Health Services. 2014. Available at: http://www.dhs.kerala.gov.in/docs/orders/combined.pdf. Accessed 27 September 2017

18. State Drugs Controller Office, Government of Kerala. Database of registered private pharmaceutical retail outlets. Available at: http://xlnindia.gov.in/frm_G_Cold_S_Query.aspx?ST=GJ. Accessed 27 September 2017

19. Kerala Medical Services Corporation Limited. Information about services provided by KMSCL. Available at: http://www.kmscl.kerala.gov.in/. Accessed 27 September 2017

20. Sarma, S., Baldridge, AS. Deidentified data and analytic code from cross-sectional field survey of 199 pharmacies in Kerala. GitHub, Inc; 2017. Available at: https://github.com/smitha48f/Tobacco-Meds-Kerala-2017

21. AIOCD Pharmasofttech AWACS Pvt. Ltd. Pharmatrac Database. Available at: www.aiocdawacs.com/ProductDetail.aspx. Accessed 27 September 2017

22. Huffman MD, Mohanan PP, Devarajan R, Baldridge AS, Kondal D, Zhao L, Ali M, Lloyd-Jones DM, Prabhakaran D. Acute coronary syndrome quality improvement in Kerala (ACS QUIK): Rationale and design for a cluster-randomized stepped-wedge trial. Am Heart J. 2017; 185:154–160. [PubMed: 28267469]

23. Huffman MD, Rao KD, Pichon-Riviere A, Zhao D, Harikrishnan S, Ramaiya K, Ajay VS, Goenka S, Calcagno JI, Caporale JE, Niu S, Li Y, Liu J, Thankappan KR, Daivadanam M, van Esch J, Murphy A, Moran AE, Gaziano TA, Suhrcke M, Reddy KS, Leeder S, Prabhakaran D. A cross-sectional study of the microeconomic impact of cardiovascular disease hospitalization in four low- and middle-income countries. PLoS ONE. 2011; 6:e20821–10. [PubMed: 21695127]

24. Cameron A, Ewen M, Ross-Degnan D, Ball D, Laing R. Medicine prices, availability, and affordability in 36 developing and middle-income countries: a secondary analysis. Lancet. 2009; 373:240–249. [PubMed: 19042012]

25. Lekshmi S, Mohanta GP, Farooq A, Manna PK. Quality and availability of medicines in public health facilities of Kerala, Indian state: An analysis. Intl J of Advances in Sci Eng Tech. 2014; 2:95–97. Available at: http://www.iraj.in/journal/journal_file/journal_pdf/6-87-142044869595-97.pdf. Accessed 27 September 2017.

26. Kotwani A. Where are we now: assessing the price, availability and affordability of essential medicines in Delhi as India plans free medicine for all. BMC Health Serv Res. 2013; 13:285. [PubMed: 23885985]

27. Khatib R, McKee M, Shannon H, Chow C, Rangarajan S, Teo K, Wei L, Mony P, Mohan V, Gupta R, Kumar R, Vijayakumar K, Lear SA, Diaz R, Avezum A, Lopez-Jaramillo P, Lanas F, Yusoff K, Ismail N, Kazmi K, Rahman O, Rosengren A, Monsef N, Kelishadi R, Kruger A, Puoane T, Szuba A, Chifamba J, Temizhan A, Dagenais G, Gafni A, Yusuf S, PURE study investigators. Availability and affordability of cardiovascular disease medicines and their effect on use in high-income, middle-income, and low-income countries: an analysis of the PURE study data. Lancet. 2016; 387(10013):61–69. [PubMed: 26498706]

28. West R. Impact of UK policy initiatives on use of medicines to aid smoking cessation. Tob Control. 2005; 14(3):166–171. [PubMed: 15923466]

29. National Tobacco Control Programme. Tobacco dependence treatment guidelines. 2011. Available at: http://www.tabaccologia.it/PDF/India%20treatment%20guidelines%20in%20English%202011.pdf. Accessed 27 September 2017

30. Department of Pharmaceuticals, Government of India. National Pharmaceuticals Pricing Policy, 2012 (NPPP-2012). The Gazette of India. 2012. Available at: https://www.jetro.go.jp/ext_images/world/asia/in/ip/pdf/nppp_2012_en.pdf. Accessed 27 September 2017

31. Bazargani YT, Ewen M, de Boer A, Leufkens HG, Mantel-Teeuwisse AK. Essential medicines are more available than other medicines around the globe. PLoS One. 2014; 9(2):e87576. [PubMed: 24533058]

32. Twagirumukiza M, Annemans L, Kips JG, Bienvenu E, Van Bortel LM. Prices of antihypertensive medicines in sub-Saharan Africa and alignment to WHO's model list of essential medicines. Tropical Medicine & International Health. 2010; 15(3):350–61. [PubMed: 20070634]

33. Tobacco Free Initiative. Proposal for inclusion of nicotine replacement therapy in the WHO Model List of Essential Medicines. 2008. Available at: http://www.who.int/selection_medicines/committees/expert/17/application/NRT_inclusion.pdf. Accessed 27 September 2017

34. Jha P, Ramasundarahettige C, Landsman V, Rostron B, Thun M, Anderson RN, McAfee T, Peto R. 21st-century hazards of smoking and benefits of cessation in the United States. New Eng J Med. 2013; 368(4):341–50. [PubMed: 23343063]

35. Critchley JA, Capewell S. Mortality risk reduction associated with smoking cessation in patients with coronary heart disease. JAMA. 2003; 290(1):86. [PubMed: 12837716]

36. Wirtz VJ, Kaplan WA, Kwan GF, Laing RO. Access to medications for cardiovascular diseases in low- and middle-income countries. Circulation. 2016; 133:2076–2085. [PubMed: 27217433]

What is known

- India is the world's second largest consumer of tobacco, but tobacco cessation remains uncommon.

- Less than 5% of Indian smokers use medications during a quit attempt despite evidence of their effectiveness.

What this study adds

- We evaluated the availability, sales, and affordability of nicotine replacement therapy, bupropion and varenicline in the south Indian state of Kerala to understand potential reasons for underutilization.

- We found that medications are only available in the private sector and are prohibitively expensive for most tobacco users.

- Incorporation of cessation medicines into the state and national essential medicines lists represents an important opportunity to introduce cessation pharmacotherapy into the public sector and to improve quit rates in Kerala and other states in India.

Table 1

Availability of cessation medicines (nicotine replacement therapy, bupropion or varenicline) in public, private, specialty and Karunya pharmacies in Kerala separated by level of care.

Level of Care	Total facilities available in the 5 districts*	Public Hospital		Public Specialty Center		Private		Karunya		Total facilities surveyed
		Surveyed	N (%) of outlets with medication available	Surveyed	N (%) of outlets with medication available	Surveyed	N (%) of outlets with medication available	Surveyed	N (%) of outlets with medication available	
General hospital	6	6	0 (0%)	0	–	12	10 (83%)	0	–	18
District hospital	6	6	0 (0%)	0	–	10	6 (60%)	0	–	16
Taluk hospital	34	10	0 (0%)	0	–	20	13 (65%)	0	–	30
Community health center	87	10	0 (0%)	0	–	20	14 (70%)	0	–	30
Primary health center	289	20	0 (0%)	0	–	37	19 (51%)	0	–	57
Chest/Tuberculosis hospital	8	6	0 (0%)	0	–	10	7 (70%)	0	–	16
Specialty center	26	0	–	10	0 (0%)	0	–	0	–	10
Karunya depot	4	0	–	0	–	0	–	4	3 (75%)	4
Karunya outlet	48	0	–	0	–	0	–	18	3 (17%)	18
Total	508	58	0 (0%)	10	0 (0%)	109	69 (63%)	22	6 (27%)	199

*
Private pharmacies excluded.

Table 2

Availability of cessation medicines (nicotine replacement therapy, bupropion or varenicline) in private and Karunya pharmacies in Kerala by district.

District	Private		Karunya		Total		
	Surveyed	N (%) of outlets with medication available	Surveyed	N (%) of outlets with medication available	Surveyed	N (%) of outlets with medication available	Odds (95% CI) of availability
Ernakulam	23	17 (74%)	5	2 (40%)	28	19 (68%)	2.6 (0.8, 8.4)
Kollam	22	12 (55%)	3	0 (0%)	25	12 (48%)	1.1 (0.3, 3.7)
Kozhikode	20	17 (85%)	5	2 (40%)	25	19 (76%)	3.9 (1.1, 13.8)
Trivandrum	26	14 (54%)	7	2 (29%)	33	16 (48%)	1.2 (0.4, 3.5)
Wayanad	18	9 (50%)	2	0 (0%)	20	9 (45%)	Ref
Total	109	69 (63%)	22	6 (27%)	131	75 (57%)	

Table 3

Cost for 12-week treatment regimens of the major brands of nicotine replacement therapy, bupropion, and varenicline sold in Kerala using the maximum retail price and the Karunya price of each medication in both absolute and relative terms (relative to maximum retail price).

Brand Name	Units per pack	Units per regimen	Private sector			Karunya sector			Relative price of Karunya regimen
			Maximum retail price per pack (Indian rupees)	Regimen Cost*		Price per pack (Indian rupees)	Regimen cost*		
				Indian rupees	US dollars		Indian rupees	US dollars	
Nicotex 2 mg gum	9	504	59	3,304	51	44	2,464	38	75%
Nicotex 4 mg gum	9	504	69	3,864	59	–	–	–	–
Bupron SR 150 mg tab	10	165	93	1,535	24	72	1,188	18	77%
Bupron XL 150 mg tab†	10	83	112	930	14	88	730	11	78%
Bupron XL 300 mg	10	83	178	1,477	23	140.5	1,166	18	79%
Champix‡				10016	154		7789	120	78%
Starter	25	1	1,516			1,179			
Maintenance	28	5	1,700			1,322			

*
The International Monetary Fund exchange rate for April 5 2017 was used: 65 Indian rupees to 1 US dollar.

†
The extended release form of bupropion at the 150 mg dose (product name: Bupron XL 150 mg) is reserved for patients who cannot tolerate higher doses.

‡
Champix by Pfizer (chemical name: varenicline) is sold as starter packs with 25 tablets per pack and maintenance packs with 28 tablets per pack. One treatment regimen consists of one starter and five maintenance packs.

Table 4

Sales of 12-week treatment regimens of nicotine replacement therapy, bupropion, and varenicline in India and Kerala from March 2013 – February 2014.

Medication	India			Kerala		
	Treatment regimens sold (n)	Sales*		Treatment regimens sold (n)	Sales*	
		Indian rupees	US dollars		Indian rupees	US dollars
Nicotine replacement therapy	166,424	354,137,400	5,705,268	7,493	16,089,625	259,209
Nicotine gum 2 mg	70,482	132,988,167	2,142,482	2,952	5,463,745	88,023
Nicotine gum 4 mg	95,942	221,149,233	3,562,786	4,541	10,625,880	171,186
Bupropion†	80,795	64,084,682	1,032,425	6,403	4,959,129	79,893
100 mg	53	75,214	1,212	–	–	–
150mg SR	33,900	31,105,345	501,117	2,288	2,139,681	34,471
150 mg XL	35,055	20,789,021	334,918	3,273	1,942,851	31,300
300 mg SR	219	104,364	1,681	–	–	–
300 mg XL	11,567	12,010,739	193,497	842	876,597	14,122
Varenicline	6051	58,451,366	941,670	196	2,020,417	32,550
Starter†‡	–	8,850,275	142,581	–	764,774	12,321
Maintenance	4981	29,423,635	474,024	191	1,128,180	18,175
0.5 mg‡	–	6,264,814	100,928	–	60,127	969
1 mg	1070	13,912,641	224,137	5	67,336	1,085
Total	**253,270**	**476,673,447**	**7,679,363**	**14,092**	**23,069,170**	**371,652**

*
The International Monetary Fund exchange rate for February 28, 2014 was used: 62 Indian rupees to 1 US dollar.

†
Bupropion is also used for other indications such as major depressive disorder so these figures are likely overestimates.

‡
Varenicline starter and maintenance packs are used together; 0.5 mg and 1 mg packs are used together.

Table 5

Median (interquartile range) reported monthly income, subsistence, and non-subsistence expenses in Indian rupees before and after hospitalization for acute coronary syndrome stratified by tobacco use status among 1716 participants in the ACS QUIK Microeconomic study.

| | N | All (n=1716) | Tobacco use at enrollment | | | Tobacco use at 30-days | | |
			Yes (n=494)	No (n=1222)	P-value	Yes (n=12)	No (n=482)	P-value
Household monthly income								
Before ACS event	1716	10,000 (8,000–18,000)	10,000 (7,000–15,000)	10,000 (8,000–20,000)	<0.001	10,500 (8,000–15,000)	10,000 (7,000–15,000)	0.90
After ACS event	1715	10,000 (5,000–15,000)	8,000 (4,000–12,000)	10,000 (6,000–15,000)	<0.001	9,000 (6,000–11,000)	8,000 (4,000–12,000)	0.69
Monthly household subsistence expenses *	1367	5,400 (3,500–8,000)	5,500 (4,000–7,500)	5,275 (3,325–8,400)	0.06	5,000 (3,600–8,800)	5,500 (4,000–7,500)	0.69
Monthly household non-subsistence Income †	1367	6,800 (3,000–11,000)	5,000 (1,600–9,000)	7,300 (4,275–12,000)	<0.001	4,500 (1,200–10,000)	5,000 (1,600–9,000)	0.62

*
Food, rent, gas, education, transport and insurance

†
Equal to zero where subsistence expenses exceed income, calculated using income prior to event

Table 6

Monthly tobacco expenditure in Indian rupees before and after hospitalization for acute coronary syndrome stratified by tobacco use status among 494 tobacco users in the ACS QUIK Microeconomic study.

Monthly tobacco expenditure	Tobacco product used					Tobacco use at 30 days		
	All tobacco users (n=494)	Only smoked (n=438)	Only chewed (n=41)	Both (n=15)	P-value	Yes (n=12)	No (n=482)	P-value
Before ACS event	150 (0–300)	200 (0–300)	50 (0–250)	300 (100–500)	0.02	375 (100–550)	150 (0–300)	0.03
After ACS event	0 (0–0)	0 (0–0)	0 (0–0)	0 (0–0)	0.82	0 (0–250)	0 (0–0)	<0.001