Original Article

Sale of antibiotics without prescription in stand-alone pharmacies in Tamil Nadu

Deena Sangeetha Chandran, Prema Prathicksha Manickavasagam

Department of Pharmacology, Saveetha Medical College, Chennai, Tamil Nadu, India

Abstract

Background: Non-prescription sale of antibiotics is one of the major causes for increased consumption of antibiotics which facilitates the emergence of drug resistance. Over-the-counter sale of antibiotics in India, without prescription and often at partial doses, is quite common even though the practice is not legal. **Objectives:** (1) To interview pharmacists about the sale of over-the-counter medication, and prescription drugs sold without a prescription, in particular; (2) to obtain an understanding of the reasons for such sale from the perspective of the pharmacist. **Methods:** Pharmacists were interviewed with the help of a pre-validated questionnaire in 15 stand-alone pharmacies in a metropolitan city and a tier-2 city in Tamil Nadu. Major points of interest were characteristics of customers requesting antibiotics without a valid prescription, common diseases for which they were sold without prescription, whether patients asked for antibiotics by name or as treatment for their symptoms, and reasons for such requests. **Results:** Pharmacists readily admitted to selling prescription drugs, including antibiotics without a valid prescription. While they know of antibiotic resistance, not a single pharmacist interviewed by us knew of the causes of antibiotic resistance. **Conclusion:** The intervention listed in the National Action Plan on Antimicrobial Resistance to develop awareness campaigns targeted at dispensers regarding existing rules and appropriate use of antimicrobials and mandatory training programs on optimal antimicrobial use must be implemented immediately.

Keywords: Antibiotic resistance, over-the-counter antibiotic sales, pharmacist survey, sale of antibiotic without prescription

Introduction

Antimicrobial resistance is a problem that is causing us to revert back to the dark ages, when antibiotics were not available.[1,2] Pan-resistant Gram-negative bacterial infections, which do not have a single sensitive antibiotic are becoming too common in India.[2] Antibiotic resistance has been linked to high levels of antibiotic usage among the community.[3] Multi-drug resistant bacteria evolve locally under the pressure of excessive antibiotic use, with horizontal gene transfer providing the means by which drug-resistant genes spread amongst different bacterial species and strains.[4] Self-medication with antibiotics contributes significantly to this in most of the developing countries. Only northern Europe and North America implement proper curbs on the sale of antibiotics without prescription.[1]

Antibiotic resistance is more severe in developing countries where the burden of infectious diseases is higher and healthcare spending is low.[5]

Non-prescription sale of antibiotics is one of the major causes for increased consumption of antibiotics which facilitates the emergence of drug resistance.[5] Over-the-counter (OTC) sale of antibiotics in India, without prescription and often at partial doses, is quite common, even though the practice is illegal.[6]

In India, the term *OTC* has no legal recognition. All drugs that come under Schedule H and Schedule X of the Drugs and Cosmetics Rules, 1945, legally require a prescription for their sale.

Address for correspondence: Dr. Deena Sangeetha Chandran, Department of Pharmacology, Saveetha Medical College, Chennai, Tamil Nadu, India.
E-mail: deenasangeetha@gmail.com

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All other drugs are "non-prescription drugs".[7] Antimicrobial agents (AMAs) come under Schedule H and H1.[8] Though antibiotics are to be sold only with a valid prescription, this rule is not enforced, and in India, antibiotics are freely available without a prescription.[7,8] All healthcare providers must be aware of all of the factors contributing to antimicrobial resistance, even those that are not immediately modifiable by them.

Methodology

The objectives of our study were (1) to interview pharmacists about the sale of OTC medication, with emphasis on prescription drugs sold without a prescription; (2) to obtain an understanding of the reasons for such sale from the perspective of the pharmacist.

Ethical clearance was obtained from the Institutional Review Board of the medical college that the authors are affiliated to. Though the participant contact details were noted in the written informed consent, these were not noted in the questionnaire to preserve anonymity.

Fifteen stand-alone pharmacies were selected in Chennai and a tier-2 city in Tamil Nadu, India. Written informed consent was obtained. The investigators then discretely observed sales for about 15–30 minutes, and in-depth interviews were conducted with a questionnaire, with the responses noted down. The questionnaire was an open-ended interview checklist designed to ascertain prevailing dispensing practices. The questionnaire was validated by obtaining responses from a friendly neighborhood pharmacy. The following details were collected: characteristics of customers requesting antibiotics without a valid prescription, common diseases for which antibiotics were sold without prescription, whether patients asked for antibiotics by name or as treatment for their symptoms, and reasons why they requested for sale of antibiotics without a prescription.

Results

The demographic profile of the pharmacists who were part of this study and majority of their customers is found in Table 1.

An average of 38% (28%–75%) of drug sales per day were without prescription. Drugs sold without prescription included both prescription (Schedule H) medications and those that did not appear in any restrictive schedule.

The most common diseases for which customers requested treatment were cough and cold ($n = 13$). Other diseases mentioned were headache ($n = 2$), diarrhea ($n = 2$), myalgia ($n = 2$), joint pain ($n = 1$) and indigestion ($n = 1$).

While customers often requested medication for elders at home by describing their symptoms, this was a rare occurrence for children.

All the pharmacists interviewed ($n = 15$) accepted readily that they sold prescription medication over the counter. The brands dispensed during such sale were chosen based on what each pharmacist perceived to be of good quality. Most pharmacists said that the majority of patients requesting medication without prescription asked for drugs to treat symptoms described ($n = 9$, 60%). Few pharmacists, however, said that a majority of their patients asked for medications by brand name ($n = 6$, 40%). When questioned as to how the patients knew which medicines to ask for, they said that patients would have old prescriptions (their own, or borrowed from family member or friend) or used strips of medicine which they had used for relief of similar symptoms in the past.

When asked specifically if they sold antibiotics without prescription, only 7 out of the 15 pharmacies (46.7%) interviewed accepted that they did so. Some of these pharmacies did not readily admit to the sale of antibiotics without prescription but had to be coaxed in a friendly manner to do so. The antibiotics preferred for such sale included amoxycillin, co-amoxiclav, azithromycin, levofloxacin and metronidazole. Unfortunately, only a tiny minority of patients who purchased antibiotics, both with and without a prescription, bought the whole course. These patients preferred to buy medicines for 1–3 days, either due to lack of money or because they knew they would recover after taking a few doses.

The reasons cited by these patients who purchased antibiotics over the counter were "lack of time", "to avoid costly doctor fees" and that "the same drug was prescribed each time".

All the pharmacists interviewed were aware about the existence of antibiotic resistance. However, they were woefully misinformed about the causes of drug resistance. A shocking majority of them ($n = 7$) described "a lack of immunity" as the reason for antibiotic resistance. Other reasons cited were "poor hygiene" ($n = 3$), "lack of availability of effective antibiotics" ($n = 2$) and "irregular intake of dispensed antibiotics" ($n = 3$).

Almost all of the pharmacists interviewed ($n = 14$), agreed that the sale of antibiotics without prescription was not good. When asked why they thought so, the reasons were varied, the most common being overuse, misuse or abuse of the drug, more adverse effects, patients being unaware of the drug's side effects. One pharmacist opined that the sale of antibiotics without prescription was good, as drugs would be easily available in case of emergencies.

Discussion

Our study demonstrates that antibiotics are easily sold without prescription, even though the law prohibits such sale.

The findings from our study were consistent with other similar studies. Saradamma RD *et al.*[9] also reported that people with

lower levels of education and socioeconomic class were more likely to purchase medications without a prescription.

Ravichandran *et al.*[7] in Kolar interviewed 112 pharmacists with a questionnaire to obtain their perception regarding dispensing of OTC medications. The symptoms for which patients requested medications over the counter in their study were similar to the results obtained from our study. Their study also reported that 10% of medications dispensed without prescription were antimicrobials. A World Health Organization (WHO) report on the evolving threat of antimicrobial resistance estimates that antibiotics are the second most common drugs used for self-medication, after analgesics.[10]

Only 7 out of 15 pharmacists (46.7%) interviewed in our study acknowledged that they sold antibiotics over the counter without prescription. However, in a simulated client study in Pune by Salunkhe SD *et al.*,[12] 248 out of 263 pharmacies (94%) dispensed antibiotics to investigators posing as patients. In another simulated client study in Pune, Rathnakar UP *et al.*[8] showed that 51.7% of pharmacies freely dispensed antibiotics without a prescription. In a community survey, Hanumantharayappa *et al.*[11] stated that antibiotics constituted 27% of all drugs sold without prescription in urban areas, while this dropped to 8% in rural areas.

Salunkhe SD *et al.*[12] reported that antibiotics were dispensed without prescription for sore throat and diarrhea in 92.48% and 96.15% cases, respectively. Azithromycin and norfloxacin were commonly given. Antibiotics were dispensed in correct doses and duration for sore throat and diarrhea in 64.22% and 10.4% cases, respectively. Only 2% of pharmacies asked about history of drug allergy and 8% recommended obtaining a physician's advice. Pharmacists participating in our study also admitted that they did not sell the entire course of antibiotics or ask about history of allergies or gestational status.

Our study shows that the sale of antibiotics without prescription is not just patients seeking antibiotics (by name) as self-medication, but patients seeking to consult the pharmacist to prescribe the antibiotic instead of losing time and money over consulting a doctor. The pharmacist is not legally allowed to prescribe antibiotics. Our study was not able to ascertain whether the patients were aware that what they were doing was illegal.

The illegal error of dispensing antibiotics without prescription is further compounded by selling these antibiotics in improper doses and duration, contributing grossly to the problem of antibiotic resistance. Freely available antibiotics, without the gatekeeper effect of a required prescription, creates an opportunity for overuse and inappropriate use of antibiotics.[6] Studies have also shown that pharmacies in the private sector sell mainly newer antibiotics like fluoroquinolones and cephalosporins, promoting the spread of resistance in the community to the newer drugs as well.[1,13]

On comparing two separate studies where the investigators posed as simulated patients to pharmacies, both conducted in the same city, Pune, one year apart, it is observed that there is a gross increase in the percentage of pharmacies prescribing antibiotics to the simulated patients. In the study by Salunkhe SD *et al.*,[12] 248 out of 263 pharmacies (94%) prescribed antibiotics in 2013. However, in the previous study by Rathnakar UP *et al.*,[8] in 2012, only 31 out of 60 pharmacies (51.7%) prescribed antibiotics to simulated clients. This shows that the prevalence of this illegal practice of pharmacists prescribing antibiotics to patients has increased greatly. Both of these simulated client studies document that the illegal practice of pharmacists prescribing antibiotics continues unchecked as the government does not enforce existing laws restricting sale of Schedule H drugs without prescription.

In a study by Dua V *et al.*,[14] pharmacists viewed themselves as businessmen rather than dispensers, and rarely offered unsolicited advice. They also noted that the number of tablets sold in a prescription was limited by the purchasing power of the patient.[14,15]

Pharmacists in our study were questioned about how they chose which antibiotic or other prescription medication to prescribe, and all of them uniformly replied that the choice was made based on quality. But other studies interviewing pharmacists about their practices reported that they mimicked the prescribing habits of prominent doctors in the locality.[1,7,15] They also felt that health education of the public through television, radio and social media would be most effective in curbing the seeking of antibiotics through pharmacies.[15]

Our study shows that many pharmacists, shockingly, all of our study participants, are unaware of the causes of antibiotic resistance. Government policies to educate pharmacists about the harm caused by illegal sale of antibiotics without prescription and the causes of drug resistance is the need of the hour. The government must also undertake a massive health education program to the general public about factors causing antibiotic resistance, the perils of non-availability of effective antibiotics, and to avoid consumption of antibiotics without a valid prescription. Similar suggestions for interventions were made by pharmacists themselves in a study by Kotwani *et al.*,[15] which involved focus group discussions retail pharmacists, public sector pharmacists and the office bearers of pharmacists' associations in Delhi.

The general public can be further incentivized to consume antibiotics only with a physician's prescription by highlighting the incidence of adverse drug reactions with antimicrobials. Of adverse events requiring emergency room admission, 19% were due to antimicrobials.[16] And multiple studies have documented that pharmacists rarely asked patients about prior drug allergies or inquired if the patient was pregnant or a lactating mother.[1,8,17]

Pharmacists in other studies,[15,18] as well as our own, felt that pharmacists needed to be educated about factors that led to

antibiotic resistance and rational prescribing. This is a crucial step that needs to be implemented immediately. Even if it is not always possible to implement laws restricting sale of antibiotics without prescription, educating pharmacists about rational prescribing will at least ensure that the right antibiotics at appropriate doses and duration of therapy are given. Internationally, there is evidence that awareness generation campaigns in combination with other interventions that are organized at the national level may be successful to reduce antibiotic use.[19]

While the contribution of physicians' antibiotic prescription practices to increasing antibiotic resistance has been well documented,[20] the role of antibiotic sale without prescription has been largely neglected in India. OTC sale of antibiotics can lead to gross increase in resistance rates.[5] Continuing education programs, hospital antibiotic policies, and hospital infection-control audits of antibiotic prescriptions are all aimed at improving prescribing practices amongst doctors. These are all for naught if the contribution to illegal OTC sale of antibiotics to increasing prevalence of antibiotic resistance is overlooked. Antibiotic use is more outside the hospitals than inside them.[1,21,22] But interventions to preserve the effectiveness of antibiotics are largely focused on hospitals and doctors' prescribing patterns, and have missed recognizing or even acknowledging the contribution of non-prescription antibiotic use.[1]

Enforcing basic regulation restricting sale of antibiotics without prescription has been proven to cause a sharp decrease in antibiotic consumption.[23] The government has been negligent in its duties in this regard, and has chosen to turn a blind eye to this widely prevalent problem, in spite of increasing prevalence of multi-drug resistant bacteria. Such rampant sale of antibiotics without prescription is unlikely to occur without the tacit approval of local regulatory staff.[24]

Even if the government ordered more frequent regulatory visits and harsher penalties, it is likely that some regulatory violations would continue, as drug stores have strong financial incentives to operate outside official regulations.[24] But it is known that pharmacies in India refrain from selling sedatives and opioids without prescription. They may refill an old, possibly invalid prescription, but they do not dispense sedatives without a prescription.[25]

Pharmacists have also voiced their suggestion that pharmacies participating in rational use of antibiotics should be awarded some recognition or appreciation by the relevant authorities, which would be useful to them in turn to market to their customers.[15]

Porter G *et al.*,[6] reviewed original research articles to characterize the extent of medication misuse in India and to understand the underlying factors involved. Their review revealed that health care providers expressed that poor script regulation, the ability for unqualified practitioners to write prescriptions, unregulated dispensing of medications and weak drug policy, all serve as primary causes of medication misuse. Pharmacists themselves feel that regulatory authorities must enforce existing laws against sale of antibiotics without a valid prescription, and preventing sale of drugs in smaller quantities than those prescribed by the doctor.[1,5,15,18]

Table 1: Demographic Profile of Pharmacists and Their Customers

	Pharmacist (*n*=15)	Patients purchasing without prescription (as described by pharmacists)
Age Range	35-54 years (mean=48.2 years)	30-60 years
Gender	Male	Mostly male
Work Experience	10-30 years	Not Applicable
Qualification	B. Pharm	Mostly illiterate

Ethically, it may be difficult, or even impermissible to restrict access to lifesaving antibiotics, especially in rural areas, where access to health care is limited.[6,24] Even restriction of sale of incomplete courses of antibiotics may be problematic, as patients in our country are often unable to pay for a full course. But in urban areas, with higher population density and higher prevalence of antibiotic resistance,[26,27] the laws regulating sale of antibiotics without prescription must be strictly enforced. This must be done immediately, on a war footing, if we are to have any hope in not returning to a pre-antibiotic era.

We are at a crucial point in the war against the increasing prevalence of antimicrobial resistance in India, driven by rampant overuse of antibiotics in medicine, as well as horticulture and animal husbandry. Antibiotic overuse amongst patients is facilitated to a large extent by the free availability of these drugs without prescription, throughout India.[28] Easy accessibility of primary care physicians by patients for common ailments can help to reduce the practice of seeking medical care from pharmacists.

Conclusion

Community antibiotic stewardship is the new watchword. A focus on non-prescription antimicrobial sale is essential to curtail antibiotic resistance. A three-pronged intervention strategy will reap rewards: health education to the general public and to the pharmacists about the personal and societal perils of antibiotic resistance, the factors that cause it, and lastly, ranking and recognizing pharmacies publicly based on their sale of prescription medication only. Strategies that lean too heavily solely on professional education or punitive damages are unlikely to result in large-scale or long-lasting improvement.

We conclude that it is the need of the hour for the government to consider pharmacies as a significant factor in antibiotic resistance and plan for specific educational measures to raise awareness on the causes of antibiotic resistance. It would also be prudent to restrict the sale of higher antibiotics, similar to Schedule X

medications. Primary care physicians will need to stand in the gap created to fill the healthcare needs of our population.

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Conflicts of interest

There are no conflicts of interest.

References

1. Morgan DJ, Okeke IN, Laxminarayan R, Perencevich EN, Weisenberg S. Non-prescription antimicrobial use worldwide: A systematic review. Lancet Infect Dis 2011;11:692-701.
2. Abdul Ghafur K. An obituary--on the death of antibiotics! J Assoc Physicians India 2010;58:143-4.
3. Almaaytah A, Mukattash TI, Hajaj J. Dispensing of non-prescribed antibiotics in Jordan. Patient Prefer Adherence 2015;9:1389-95.
4. Hawkey PM, Jones AM. The changing epidemiology of resistance. J Antimicrob Chemother 2009;64(Suppl 1):i3-10.
5. Gebretekle GB, Serbessa MK. Exploration of over the counter sales of antibiotics in community pharmacies of Addis Ababa, Ethiopia: Pharmacy professionals' perspective. Antimicrob Resist Infect Control 2016;5:2.
6. Porter G, Grills N. Medication misuse in India: A major public health issue in India. J Public Health 2016;38:e150-7.
7. Ravichandran A, Basavareddy A. Perception of pharmacists regarding over-the-counter medication: A survey. Indian J Pharmacol 2016;48:729-32.
8. Rathnakar UP, Sharma NK, Garg R, Unnikrishnan B, Gopalakrishna H. A study on the sale of antimicrobial agents without prescriptions in pharmacies in an urban area in South India. J Clin Diag Res 2012;6:951-4.
9. Saradamma RD, Higginbotham N, Nichter M. Social factors influencing the acquisition of antibiotics without prescription in Kerala State, South India. Soc Sci Med 2000;50:891-903.
10. Torres NF, Solomon VP, Middleton LE. Patterns of self-medication with antibiotics in Maputo City: A qualitative study. Antimicrob Resist Infect Control 2019;8:161.
11. Hanumantharayappa NB, Siddaiah SN. Use of over the counter drugs in urban and rural populations of Mandya district: A cross-sectional study. Int J Basic Clin Pharmacol 2016;5:1617-21.
12. Salunkhe SD, Pandit VA, Dawane JS, Sarda KD, More CS. Study of over the counter sale of antimicrobials in pharmacy outlets in Pune, India: A cross sectional study. Int J Pharma Bio Sci 2013;4:616-22.
13. Holloway K, Mathai E, Gray A. Surveillance of community antimicrobial use in resource-constrained settings--experience from five pilot projects. Trop Med Int Health 2011;16:152-61.
14. Dua V, Kunin CM, White LV. The use of antimicrobial drugs in Nagpur, India. A window on medical care in a developing country. Soc Sci Med 1994;38:717-24.
15. Kotwani A, Wattal C, Joshi PC, Holloway K. Irrational use of antibiotics and role of the pharmacist: An insight from a qualitative study in New Delhi, India. J Clin Pharm Ther 2012;37:308-12.
16. Shehab N, Patel PR, Srinivasan A, Budnitz DS. Emergency department visits for antibiotic-associated adverse events. Clin Infect Dis 2008;47:735-43.
17. Bin Abdulhak AA, Altannir MA, Almansor MA, Almohaya MS, Onazi AS, Marei MA, *et al.* Non prescribed sale of antibiotics in Riyadh, Saudi Arabia: A cross sectional study. BMC Public Health 2011;11:538.
18. Torres NF, Solomon VP, Middleton LE. Pharmacists' practices for non-prescribed antibiotic dispensing in Mozambique. Pharm Pract (Granada) 2020;18:1965-77.
19. National Action Plan on Antimicrobial Resistance (NAP-AMR) 2017 – 2021. National Centre for Disease Control, Ministry of Health & Family Welfare, Govt of India. Available from: https://www.ncdc.gov.in/WriteReadData/linkimages/AMR/File645.pdf.
20. World Health Organization. Worldwide Country Situation Analysis: Response to Antimicrobial Resistance. WHO Press; 2015. p. 1-50. Available from: https://apps.who.int/iris/bitstream/handle/10665/163468/9789241564946_eng.pdf;jsessionid=BA59BDEC6715AC89B69E62B5ED527915?sequence=1. ISBN: 978 92 4 156494 6.
21. Oleim SH, Noor SK, Bushara SO, Ahmedet MH, Elmadhoun W. The irrational use of antibiotics among doctors, pharmacists and the public in river Nile state, Sudan. Sudan J Med Sci 2019;14:276-88.
22. Wise R, Hart T, Cars O, Streulens M, Helmuth R, Huovinen P, *et al.* Antimicrobial resistance is a major threat to public health. BMJ 1998;317:609-10.
23. Seppälä H, Klaukka T, Vuopio-Varkila J, Muotiala A, Helenius H, Lager K, *et al.* The effect of changes in the consumption of macrolide antibiotics on erythromycin resistance in group A streptococci in Finland. Finnish study group for antimicrobial resistance. N Engl J Med 1997;337:441-6.
24. Goodman C, Kachur SP, Abdulla S, Bloland P, Mills A. Drug shop regulation and malaria treatment in Tanzania--why do shops break the rules, and does it matter? Health Policy Plan 2007;22:393-403.
25. Nattala P, Murthy P, Thennarasu K, Cottler LB. Nonmedical use of sedatives in urban Bengaluru. Indian J Psychiatry 2014;56:246-52.
26. Bruinsma N, Hutchinson JM, van den Bogaard AE, Giamarellou H, Degener J, Stobberingh EE. Influence of population density on antibiotic resistance. J Antimicrob Chemother 2003;51:385-90.
27. Kotwani A, Joshi J, Lamkang AS. Over-the-counter sale of antibiotics in India: A qualitative study of providers' perspectives across two states. Antibiotics 2021;10:1123.
28. Porter G, Kotwani A, Bhullar L, Joshi J. Over-the-counter sales of antibiotics for human use in India: The challenges and opportunities for regulation. Med Law Int 2021:21:147-73.