

Selling Drugs Over-the-Counter in Larkana: A Cross-Sectional Study

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Abstract

Objectives: (1) to determine the frequency of selling the drugs over-the-counter in Larkana; (2) to assess the factors causing the selling of drugs OTC; (3) to assess the registry of medical stores of Larkana.

Methods: A cross-sectional study was accomplished in Larkana. For sampling purpose Larkana city was arbitrary divided into five zones: east, west, south, north, and central. Then 25 medical stores randomly selected from the central zone because the majority of the stores were situated in the centre of city while 15 medical stores were randomly selected from east, west, north & south respectively. A pre-tested structured questionnaire was developed to collect data. It was filled by investigator himself. Data was evaluated by SPSS version 17.

Results: In our study it was found that 75.3% of the stores were holding the license; about 74.1% of the drugs sellers sell the prescription-only drugs over the-counter. Factors causing this act were: (1) abuse of drugs 52%, (2) lack of professional care 48%. According to drug sellers the causes of selling OTC drugs were due to (1) lack of implementation of law 53% and (2) lack of awareness of people 35%.

Conclusion: Steps should be taken for the establishment of a regulation body to oversee the selling of drugs. Health-care environment emphasizing awareness among the people could bring a change in reducing the abuse of drugs.

Keywords: over-the-counter (OTC), professional-care environment

Introduction

The drugs which need to be sold with prescription-only, are being sold over-the-counter, this makes it worse as medication is being mishandled, and “the goal of medication is to prevent, cure or control various diseases states. To achieve this, adequate drug doses must be delivered to the target tissues. Thus, the clinician has to recognize the onset and duration of drug action and the intensity of drug’s effect (Lippincott, 2013). For prescribing a medicine for a certain type of disease, one needs to study various subjects like human physiology, pathology, biochemistry, pharmacology and other subjects and also have extensive training in them. Only a doctor has approached the peak of these subjects and which makes a doctor perfectly able enough to prescribe a suitable drug to the patient. Therefore the job of prescribing the drugs is only given to these graduated, qualified and trained doctors. Acting like a doctor is easy these days that even a dispenser indulges in these activities and our society is surrounded by these quacks. And due to this, contagious diseases remain undiagnosed and the person without any proper evaluation takes drugs just for symptomatic relief and without any knowledge a deadly disease harbor in the person. It is also the reason for resistance of many drugs.

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Drugs can be of various types, but on the basis of sales of drugs they are classified into two main types i-e ones are called over-the-counter (OTC) drugs, these are sold to consumer without any prescription from a health care professional because they are not as harmful as the other type which is prescription-only drugs, these drugs to be sold to consumer need a prescription otherwise they are not to be sold, because these drugs need to be dose and dosage adjusted and risk-benefit measured. Most of the countries regulate OTC drug by a named department to secure the use of their products to be safe and effective without any practitioner's care. Active pharmaceutical ingredients (APIs) regulate the OTC drugs while final products do not. Due to this the manufacturers are free to formulate ingredients or their combinations, into proprietary mixtures (FDA, 2013a). There are many benefits of selling the drugs without the need of prescription as these OTC drugs give relief for many disturbing symptoms and may cure some diseases simply without seeing a doctor. But however, to use these drugs one should have appropriate awareness, education, and responsibility.

Aspirin and acetaminophen are typically considered as OTC, but in addition to these drugs federal Food and Drug Administration (FDA) also recognizes other available products. Some toothpaste, mouth washes, some types of eye drops and ointments, wart removers and first aid creams and even dandruff shampoos are declared OTC. FDA only approves those drugs as over-the-counter sale which have excellent safety records and for years have been regulated by prescription. Famotidine and ibuprofen come in the category of these drugs. OTC version of a drug often has a considerably lower amount of active ingredient in each form of tablet, capsule or caplet than the prescription-only drugs.

But there are exceptions to the safety and effectiveness of OTC drugs, for example a sleep aid diphenhydramine is neither as effective nor as safe especially in older people (Lynch, 2019). And some substances are completely prohibited over-the-counter because these products having OTC status from the FDA are comprised by an indefinite third category of substances, while being at the same time subject to other restrictions on sale. When a drug is legally classified as OTC, it is only stored behind the counter and are sold only in legally registered stores. Such products have become unavailable in stores. For example, many US medical stores have shifted products containing pseudoephedrine, an OTC drug, into places where the purchaser must ask a druggist for them. In order to reduce methamphetamine production, an effort has been made even though prescription is not required. The purchase of pseudoephedrine in the United States is restricted after the Illinois Methamphetamine Precursor Control Act and federal Combat Methamphetamine Epidemic Act of 2005. It limits the pharmacies from selling any package above the restricted quantities. The identity of the customer must be obtained and recorded. In some states of United States of America, there are even more difficult requirements such as in Oregon, where prescription is required to buy pseudoephedrine. Even with these limitations, products containing the pseudoephedrine are still over-the-counter in most states.

Some forms of emergency contraception are also regulated. As levonorgestrel is prescription-only drug in United States but is available over-the-counter in many other countries (Fenichel, 2004). For females having age 17 or above, these products are OTC, but need prescription for females below the described age (FDA, 2009). For enforcing this limitation over the product and to spread awareness and education among the people, there was an agreement between the manufacturer and the FDA, which requires that women should give evidence of age to pharmacist and receive important education of the drug if a prescription is not present (FDA, 2013b).

In Pakistan, there is no any regulatory body which registers and regulates the drugs. With just a recommendation from a pharmacist or a quack common person can purchase prescription-only drugs over-the-counter. There is always a danger of over dosage or misuse of these drugs. There are not much studies conducted on selling the over-the-

counter in Pakistan. It is simply obvious that a particular rule and law is in need to restrain this (Peterman, 2015).

According to a study conducted in Rawalpindi, Islamabad, around 16% sellers admitted that they sold drugs without prescription (Butt et al., 2005). And in Abu Dhabi selling prescription only drugs to over the counter is common as admitted by the sellers even though knowing about the law. Common reasons given by the drug sellers was that selling the drugs OTC, was just out of the jealousy because if they did not satisfy the purchaser then other rival pharmacy would. And it further says that pharmacists are not providing professional care since they are not doctors and therefore patient care and safety are endangered (Yeboah & Yeboah, 2014). According to Pakistan Pharmacist Association (2019), there has been a wordily restriction over the sale of all potent drugs limited to only medical practitioners but we have not seen any action upon this in Larkana so there was a dire need of doing a research, a cross sectional study, in Larkana so that awareness should spread and a health care environment could be established.

Methodology

This cross-sectional survey was carried out in Larkana city from 22 September 2014 to 02 October 2014. A total of 85 medical stores were selected from Larkana by simple random sampling. And for that purpose Larkana city was arbitrary divided in to five zones east, west, and south, north and central. Thus 25 medical stores randomly selected from the central zone because the majority of the stores were situated in the centre of city while 15 medical stores were randomly selected from east, west, north & south respectively. Since it is a cross sectional study, random sampling was perfectly suitable and effective and it is also simpler to carry out. Drugs sellers were briefed or given explanation about the purpose of research.

Survey Instrument

Data was collected on pre tested structured questionnaire. The questionnaire was comprised of two segments. The first had questions on information of the medical store such as name, registration, its duration, opening and closing time etc. And the second was for questions about selling the drugs over-the-counter such as its cause, solution, responsibility etc. The pre-tested questionnaire was used so that necessary amendments must be carried out in order to achieve easy understanding and filling. It was filled by investigator himself.

Data Analysis

Data obtained with the help of the study tool (questionnaire) was assessed and calculated by Statistical Package for Social Sciences (SPSS) version 17. Frequencies and percentages were calculated for categorical variables such as registry and license, and purpose of selling the drugs over-the-counter. And the results were presented using tables.

Results

We analyzed 85 medical stores in our cross-sectional study. As Figure 1 clearly shows that 64 (75.3%) medical stores were holding the license while 21 (24.7%) were not. And according to Figure 2 about 63 (74.1%) drugs sellers sell the prescription-only drugs over the-counter. We observed average customers coming daily in one hour to stores were 113 and average 36 customers in an hour were coming without prescription.

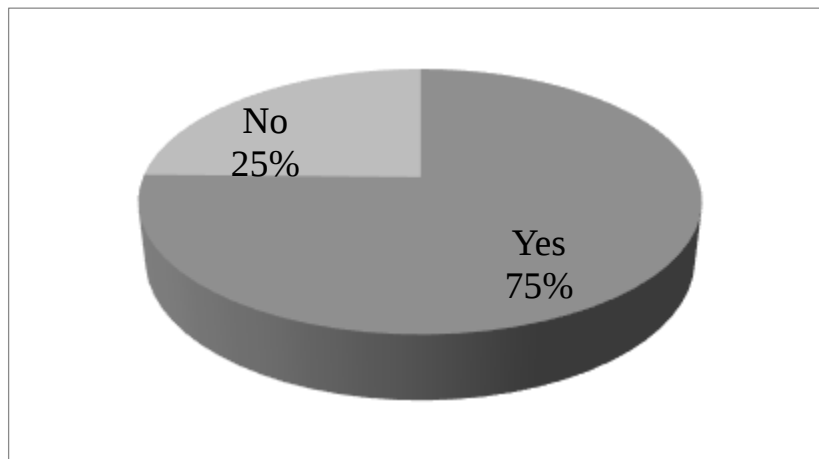


Figure 1. Registry of medical stores

Regarding the illegal act of selling the prescription-only drugs without the prescription, 69 (81.2%) drug sellers told it was wrong and 16 (18.8) said it was right. Figure 3 clearly shows that 44 (51.8%) of them described it was wrong due to abuse of drugs and 41 (48.2%) said it was wrong due to lack of professional care. Among the drug sellers who agreed upon selling the drugs over-the-counter is justified under certain circumstances were 33 (38.8%) while only 29 (34.1%) drugs sellers disagreed upon it. 35 (41.2%) rated the drug usage that was sold over-the-counter was bad and 29 (34.1%) rated it as fair. We also found out that 45 (52.9%) of the drug sellers believed that the cause of selling the drugs over-the-counter was due to lack of implementation of law while 30 (35.3%) believed it was due to lack of awareness of customers. Our study suggests that a regulation body should be established to check and balance the selling of drugs over-the-counter, 40 (47.1%) drugs sellers strongly agreed and 41 (48.2%) of them just agreed upon it.

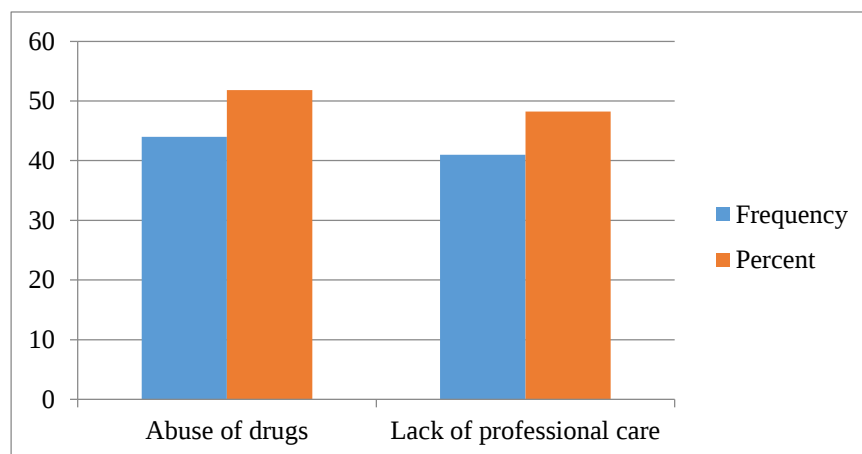


Figure 2. Selling the prescribed-only drugs OTC

Discussion

There are two types of drugs one which cannot be bought without the prescription of a doctor or any health profession; those are called “prescription-only” drugs because common man does not know the side effects and action of those drugs on the body without having the advice of a doctor. And others are those which can be bought without the prescription of doctors or any health professional those are called “Over-the-counter” drugs because those are specified drugs and approved by Health care professional only. In the United States of America, FDA controls and regulates these drugs; prescription-only drugs are regulated by a

particular process called “New Drug Application (NDA)” while over-the-counter drugs are regulated by the special monographs (FDA, 2017). Our study focuses on those prescription-only drugs which are sold over-the-counter in Larkana, and describes the dire need of a regulatory body of drugs in Pakistan.

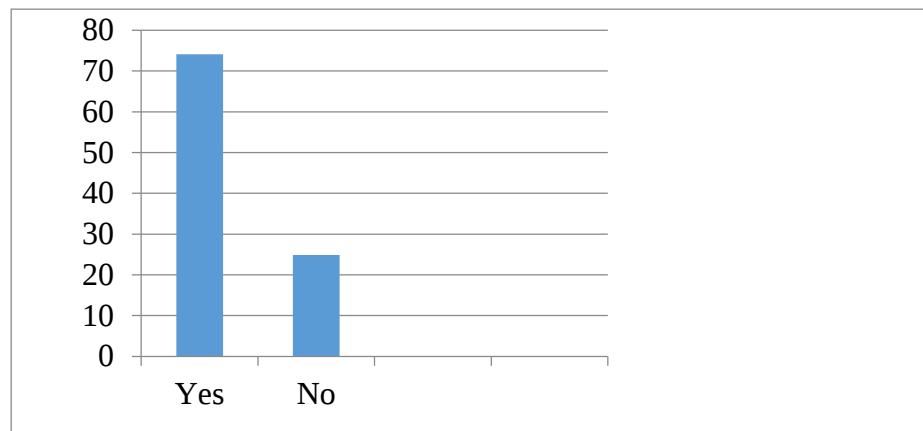


Figure 3. Causes of selling the prescribed-only drugs OTC

A study conducted in Abu Dhabi reveals that buyers said bypassing a doctor was cheaper and simpler, it was easy to obtain what they wanted, pharmacists did not mind, all their friends were doing it, and they had suffered no physical harm (Yeboah & Yeboah, 2013). Compared to this, in our study, we found that 45 (52.9%) of the drug sellers believed that the cause of selling the drugs over-the-counter was due to lack of implementation of law while 30 (35.3%) believed, it was due to lack of awareness of customers.

Self medication is also one of the contributing factors in selling drugs OTC. According to a study executed in Punjab, Pakistan, private sectors running in Pakistan facilitate 79% of primary care (Shaikh, 2015) which limits the access to primary care to poor people thereby causing self-medication and thus, person turns towards pharmacy for the purchase of prescription-only drugs without any prescription. In Pakistan amount of medicines sold over the counter is surplus about more than half sold without prescription (Mansoor, 2013). Our study provides that 74.1% drugs are sold OTC and it alarms the need of further national or provincial studies to stop this crime and for the establishment of a health-care environment.

Excessive use of drugs without any need raises the resistance to drugs and causing mutations of microorganism and creating “super bugs”, allowing spread of severe infections which are difficult to treat (Aslam et al., 2018). According to a study about nineteen risk factors were associated with quinolone-resistant *E.coli* and quinolone use was one of them (Zhu et al., 2020). If this act is not stopped it will lead to severe consequences.

In this modern world technology is in the hands of every layman. One could easily use this and take advantage by the spread of the awareness of medicine through mobile phones, television internet etc. FDA is considering using this equipment to educate the people (Krans, 2018).

Substance abuse is becoming one of the highly anticipating problems of Pakistan; about 3.5 million people are sustaining the abuse of drugs with an advancing rate of 7% yearly (Malik et al., 2012). And our study shows 52% pharmacists consider drug abuse as the cause of easily available prescription-only drugs. Pharmacy act of 1967 established the pharmacy council of Pakistan, which functions to register and control the pharmacists of Pakistan (Azhar et al., 2009).

Pharmacist plays a vital role in selling the drugs without prescription. As the pharmacist is the person who runs the medical store or pharmacy so common people usually ask the pharmacist to assist in the dose, dosage, brand name, and efficiency of drugs, thus pharmacist has full control over the sale of drugs of prescription-only or over-the-counter (Sansgiry et al., 2017). It is therefore required that the pharmacist and the pharmacy must be licensed so that necessary regulations of the drugs must be observed and controlled. But the licensure of medical stores held by a pharmacist is not yet controlled and supervised as our study shows that 24.7% of drug stores were not registered, which gives them freedom to sell and provide any type of drug.

Conclusion

Study reveals that prevalence of selling the drugs over-the-counter is very high. Main reasons and causes identified for selling the drugs over-the-counter were lack of awareness of people, lack of professional care and lack of implementation of law.

Government should take steps towards forming relevant legislation which enforce the sales of prescribed-only drugs with prescription and observe over-the-counter ones separately. A legal body should be established to create awareness about the over-the-counter drugs and prescription-only drugs to common people so that they will know the right use of drugs. In this way this unsavory practice of selling the drugs over-the-counter would stop.

References

- Aslam, B., Wang, W., Arshad, M. I., Khurshid, M., Muzammil, S., Rasool, M. H., ... & Baloch, Z. (2018). Antibiotic resistance: a rundown of a global crisis. *Infection and Drug Resistance*, 11, 1645.
- Azhar, S., Hassali, M. A., Ibrahim, M. I. M., Ahmad, M., Masood, I., & Shafie, A. A. (2009). The role of pharmacists in developing countries: the current scenario in Pakistan. *Human Resources for Health*, 7, 54.
- Butt, Z. A., Gilani, A. H., Nanan, D., Sheikh, A. L., & White, F. (2005). Quality of pharmacies in Pakistan: a cross-sectional survey. *International Journal for Quality in Health Care*, 17(4), 307-313.
- FDA (2009). *Plan B One-Step (levonorgestrel) tablet, 1.5 mg, for oral use*. FDA [Online]. Retrieved 25 December, 2012, from https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/021998lbl.pdf
- FDA (2013a). *Over-the-Counter Medicines: What's Right for You* Retrieved 20 December, 2012, from <https://www.fda.gov/drugs/choosing-right-over-counter-medicine-otcs/over-counter-medicines-whats-right-you>
- FDA (2013b). *Plan B one step. CENTER FOR DRUG EVALUATION AND RESEARCH* [Online]. Retrieved 23 November, 2019, from https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/021998Orig1s002.pdf
- FDA (2017). *Prescription Drugs and Over-the-Counter (OTC) Drugs: Questions and Answers*. Retrieved 11 January, 2020, from <https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers>.
- Fenichel, R. R. (2004). Which drugs should be available over the counter?. *BMJ*, 329(7459), 182-183.
- Krans, B. (2018). *Could Your Medication Soon Be Available Over the Counter?*. Retrieved 11 January, 2020, from <https://www.healthline.com/health-news/could-medication-be-available-over-the-counter#1>
- Lippincott, W. K. (2013). *Basics of pharmacology*. Retrieved 20 December, 2012, from <http://n-pharmacology.blogspot.com/p/basic-of-pharmacology.html>

- Lynch, S. S. (2019). *Overview of Over-the-Counter Drugs*. Retrieved 2 September, 2019, from <https://www.merckmanuals.com/home/drugs/over-the-counter-drugs/overview-of-over-the-counter-drugs>
- Malik, A. A., Nawaz, S., Tahir, A. A., Ahmed, S., Ashraf, S., Hanif, N., Aslam, J., Jamshed, I., Yawar, A., & Malik, M. R. (2012). Knowledge and awareness of harmful effect of substance abuse among users and non-users: a cross-sectional study from Bari Imam. *JPMA. The Journal of the Pakistan Medical Association*, 62(4), 412–415.
- Mansoor, H. (2013). Excessive use of drugs creating resistance to antibiotics: report. *Dawn News*. Retrieved from <https://www.dawn.com/news/1020365>
- Pakistan Pharmacist Association (2019). *Community Pharmacy (Retail Pharmacy)*. Retrieved 19 December, 2019, from <http://ppapak.org.pk/NDP.php>
- Peterman, M. (2015). *Drug Use and Addiction in the Medical Community*. Retrieved 25 December, 2019, from <https://blogs.jpmsonline.com/2015/02/24/drug-use-and-addiction-in-the-medical-community/>
- Sansgiry, S. S., Bhansali, A. H., Bapat, S. S., & Xu, Q. (2017). Abuse of over-the-counter medicines: a pharmacist's perspective. *Integrated Pharmacy Research & Practice*, 6, 1-6.
- Shaikh, B. T. (2015). Private sector in health care delivery: a reality and a challenge in Pakistan. *Journal of Ayub Medical College Abbottabad*, 27(2), 496-498.
- Yeboah, D. A., & Yeboah, T. M. (2013). Strategies to Address over the Counter Sale of Prescription Medicines in Abu Dhabi, UAE. *Greener Journal of Medical Sciences*, 3(9), 294-300.
- Yeboah, D. A., & Yeboah, T. M. (2014). Over the Counter Sale of Prescription Only Medication in Abu Dhabi, UAE: Law Enforcement or Health Ethics. *British Journal of Applied Science & Technology*, 4(7), 1128-1137.
- Zhu, D. M., Li, Q. H., Shen, Y., & Zhang, Q. (2020). Risk factors for quinolone-resistant *Escherichia coli* infection: a systematic review and meta-analysis. *Antimicrobial Resistance & Infection Control*, 9, 11.