Assessment of Compliance to Good Pharmacy Practice by Community Pharmacies of Bhaktapur and Lalitpur Districts, Nepal

Mahasagar Gyawali[1], Mitraghan Baharadar[1], Harish Singh Thapa[2], Sangam Subedi[3], Aashish Bhattarai[3], Nim Bahadur Dangi[3*]

[1]*(Janamaitri Foundation Institute of Health Sciences (JFIHS), Hattiban, Lalitpur, Nepal)*
[2]*(School of Health Science, CTEVT, Bharatpur, Chitwan)*
[3]*(School of Health and Allied Sciences, Pokhara University)*
Corresponding Author: Nim Bahadur Dangi

Abstract: The Good Pharmacy Practice (GPP) guidelines are based on thepharmaceutical care given by pharmacists. It recommends that national standards are set for the promotion of health, supply of medicines, medical devices, patient self-care, and improving prescribing and medicine use by pharmacist's activities.A cross-sectional, observational study in the community pharmacies ofBhaktapur and Lalitpur districts was carried out for three months. 150 community pharmacies were included. An indicator-based tool, consisting of 18 questionnaires was used to assess the adherence to GPP guidelines.It was observed that both the districts showed average compliance to the GPPrequirements, Lalitpur district with a slightly higher score of 59.93 % out of 41.05 compared to Bhaktapur with a score of 58.68 % out of 41.45. Both the districts notably showed poor compliance for system indicators. Bhaktapur district showed a significantly low score of 32.8% out of 6, compared to Lalitpur 45.29 % out of 7.6. The storage indicator showed highest compliance with a score of 67.4% out of 21 for Lalitpur district and 66.3 % out of 21 for Bhaktapur district.Both districts notably failed to comply with systemindicator while the storage and service indicators showed average compliance with the GPP requirements. The pharmacies of Bhaktapur district seemed to be more traditional as compared to Lalitpur district. Insufficient infrastructure, lack of computerization, lack of privacy for patients were observed as the major problems in the community pharmacies of both the districts.
Keywords: Good Pharmacy Practice, System indicator, Storage indicator, Serviceindicator, Privacy.

I. Introduction

It is obligatory, for medicine, to be prescribed, managed, dispensed, and used correctly for enhancement of its rational use. The primary sources of medicines for people in developing countries are often a combination of dispensing doctors, pharmacy departments of hospitals, pharmacies, and drug or chemist shops. Millions of people visit community pharmacies for their daily health care needs. Pharmacists are at the first point of contact in the healthcare system due to their easy accessibility. Pharmacy professionals are influential healthcare practitioners, especially concerning the promotion of safe and rational use of medicines. Lack of qualified pharmacists and standard practice guidelines and enforcement mechanisms are the primary barriers seen in the pharmacy profession of Nepal. An open economy policy leads profuse the private sector and has given rise to a proliferation of commercial private pharmacy outlets conflicting patient compliance resulting in the poor quality of pharmacy service. In Nepal, there are different legislative provisions for the regulation of medicines and to assure the availability of safe, efficacious, and quality medicines. National Drug Authority is responsible for ensuring that all medicines sold in the country are safe, effective, and handled as per GPP standards. [1] Ministry of Health and Population (MOHP) is responsible for national planning and coordination in the health sector in Nepal. Department of Drug Administration (DDA), is a national regulatory authority for medicines, pharmacy outlets, pharmaceutical companies, and drug-testing laboratories, responsible for monitoring pharmacies.

DDA is responsible for anordinary inspection to monitor community pharmacy. The quality of Pharmacy service is monitored by studying their compliance with good pharmacy practice (GPP). Unlike developed countries, Nepal does not have a sufficient number of trained officials leading periodic inspection resulting in poor compliance with GPP. Several studies have found GPP implementation in the community setting to be suboptimal. [2] Pharmacy practice was found to be suboptimal in the Low and Middle-Income Countries, including Nepal. [3] In addition to this, there is aninsufficiency of evidence about the quality of

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pharmacy service in-country. Assessment studies become essential as it points out to the deficiencies seen in the pharmacy practice and also the need for interventions to improve the current practice. [2] This study aims to explore the extent to which community pharmacies in Bhaktapur and Lalitpur comply with Good Pharmacy Practice (GPP) guidelines of Nepal and some additional standards which have been stated by FIP/WHO regarding pharmacy practice.

II. Material And Methods

The observational cross-sectional study was carried out on the community pharmacies of Lalitpur and Bhaktapur District of Nepal from May 2017 to August 2017. One hundred fifty community pharmacies were selected by the non-probability convenience method. Whereas, Wholesale pharmacy, Hospital pharmacy, and Government-run free drug distribution centers were excluded from the study.

We collected data with the help of structured questionnaires which is divided into three parts as System Indicator: prescription recording system, use of a computer, use of inventory control system; Storage Indicator: storage conditions, pharmacy hygiene, an arrangement of medicines in pharmacy; Service Indicator: personnel qualifications, working hours of personnel, additional tests provided by the pharmacy.

Then we converted the mean score obtained under each category to percent scale for each district. The results were reported as poor (<50%), average (50-75%) and good (>75%). [4] The indicator tool consisted of pretested questionnaires developed after an extensive literature review. To ensure reliability, a pilot test was conducted among 10 percent of the actual sample population whose data were not included in the study. We finalized the questionnaire after a positive result in the pilot test. For the statistical analysis of the quantitative data, we used the Statistical Package for Social Sciences (SPSS) version.Ethical approval was taken from the JF Institute of Health Sciences, Lalitpur, Nepal, and consent were taken from participants providing the required information.

III. Results

The result of this study is summarized in terms of system, storage & service indicator of community pharmacies of Lalitpur & Bhaktapur district, Nepal. (Table 2). The overall compliance to GPP indicators for Lalitpur district was found to be 59.93 %, with a mean score of 24.6 out of a possible maximum score of 41.05, suggesting average compliance. Among all, system indicator was least with a score of 3.44 out of 7.6, i.e., 45.29 % compliance followed by 56.26 % for service indicator, & storage indicator with the highest of all 67.4 %. Similarly, Bhaktapur district had an overall compliance of 58.68 %, with mean score of 24.32 out of possible maximum score of 41.45. The component showing poor compliance was system indicator with a mean score of 1.97 out of maximum score of 6, i.e., 32.8%; storage indicator and service indicator showed average compliance with scores for storage indicator being 13.92 out of 21, i.e., 66.3% and service indicator 8.426 out of 14.45, i.e., 58.31%. (Table 1).

The use of computers in community pharmacies of Lalitpur district was 74.7 % & 30.7 % in Bhaktapur district. Majorities of community pharmacies of Lalitpur district have begun to use a computer in the pharmacy for various purposes like stock management, recording prescription, implementing FEFO, recording patient's information. While it was found very less in Bhaktapur district, this shows the community pharmacies of Bhaktapur are still running traditionally and have not adapted to computerization.

Arrangements of medicine in shelves (alphabetically or therapeutic classification) were found to be 28% & 17% in Lalitpur & Bhaktapur district, respectively. 30% & 25% of pharmacies had a lock-in storage room; 84% & 64% had a storage lock system for narcotic drugs in pharmacies of Lalitpur & Bhaktapur, respectively.

The services like Blood pressure measurement 70% & 88%; Pregnancy test 40% & 54.7%; Blood Glucose measurement 13% & 28%; Cholesterol measurement 4% & 17% was found to be in Lalitpur & Bhaktapur district respectively. In addition to this, privacy for patient counseling was 40% & 53.3%, respectively, in Lalitpur & Bhaktapur district. The working hour of both district pharmacies was less than 8hrs/day. Pharmacies were opened during morning and evening time only, which directly influence the health service in this area.

Table 1: Comparisonof components of Indicators for Good Pharmacy Practice

SN	Components of Indicators		Bhaktapur (%)	Lalitpur (%)
1	Use of Computer		30.7	74.7
2	Arrangement of Medicine in Shelves		17	28
3	Lock in storage room for narcotics		25	35
4	Services			
	a.	BP Measurements	88	70
	b.	Pregnancy test	54.7	40
	c.	Blood glucose measurements	28	13

	d. Cholesterol measurements	17	4
5	Privacy for Patient Counselling	53.3	40
6	Working hour of pharmacies	<8 hours/day	<8 hours/day

Table 2: Comparison of Indicators for Good Pharmacy Practice

Indicators	Lalitpur district	Bhaktapur district
System indicator	45.29%	32.8%
Storage indicator	67.4%	66.3%
Service indicator	56.26%	58.31%
Overall compliance	59.93%	58.68%

IV. Discussion

This cross-sectional study assessed the various indicators for good pharmacy practice. The arrangement of medicine in shelves either alphabetically or therapeutically, lock in storage room for narcotics were assessed to be very poor in both districts, whereas the use of computers in Lalitpur was near to satisfactory (Table 1). Even though the Drug Act of Nepal 2035 in section 33 has suggested for keeping narcotic drugs safely, the pharmacies in both districts were observed to have low scores. The privacy for patient counseling was on average and more in Bhaktapur district in comparison to the Lalitpur district. Though the prevalence of obesity, diabetes, and hypertension is 4.1%, 9.1%, and 28.9% respectively in Nepal [5-7] the service provided by pharmacies was poor in both districtsconcerningblood glucose measurement and cholesterol whereas the scores for BP measurements in both districts seem to be satisfactory. The pharmacies were opened only for eight hours per day that directly influence the health service in these areas.

The components of indicators vary with districts, but the overall compliance of GPP is similar. The score for system indicator and storage indicators is higher for Lalitpur district, indicating better storage and systems in pharmacies of Lalitpur, whereas the score for service indicator is higher for Bhaktapur, indicating overall more and quality services provided by pharmacies of Bhaktapur. In comparison service indicators have higher scores in both districts in comparison to other indicators.

Similarly, the storage facilities for the Kathmandu valley were rated poor with a mean score of 36.3±13.9 in an earlier study. [8] Similar substandard storage practices among other non-compliances were reported in Srilanka. [9] Inappropriate storage of medicines by professionals in developing countries isthe high incidence of low-quality drugs also showed similar results. [10] Evaluation of storage practices highlighted the lack of temperature monitoring devices and alternative power supplies for refrigerators, with more than half of the pharmacies keeping vaccines irrespective of appropriate storage temperatures. A study in Karachi reported that tetanus toxoid was sold by 76% of pharmacies. However, only 8.9% had a refrigerator. [11]

Pharmacies are managed by diverse types of dispensers in terms of their qualifications, knowledge, experience, and ages. Despite the licensing requirement, the persons usually found managing pharmacies at the time of researchers' visits were often owners, salesmen, clerks, not the licensees. Even if the licensee or pharmacist is there, patients are often unlikely to meet the pharmacist. Instead, they are usually attended by a salesman. In legality, these pharmacies generally are registered by hiring a pharmacist license. [11] Similar is the case in the community pharmacies of Nepal as a similar study conducted in community pharmacies revealed majorities of pharmacies were run by 'professionalists.' However, the proportion of pharmacies run by assistant pharmacies was higher. Similarly, about half of the community pharmacies studied were run by paramedics who neither had a pharmacy degree nor undergone orientation training. [12]

V. Conclusion

Overall, the performances of community pharmacies of both the districts were mediocre at best. However, several deficiencies were seen in the case of pharmacy practice, storage facilities, and patients' accessibility to various infrastructures and services of the pharmacy, as mentioned in the legislative requirements. Pharmacy seemed to have established their place in society more as a business model rather than healthcare providers. The results of this study may be a strong argument for implementing regulatory interventions, such as GPP inspections and infrastructural development.

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