



Do community pharmacists in Nepal have a role in adverse drug reaction reporting systems?

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BRIEF REPORT

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Abstract

Community pharmacies in Nepal serve both rural and urban populations and are an integral part of the Nepalese healthcare system. These community pharmacies are run by non-pharmacist professionals with orientation training on pharmacology and drug dispensing. Graduate pharmacists' involvement in community pharmacy will help with patient counselling, dispensing of medication and promotion of safe and appropriate medicine use. Nepal has an organised pharmacovigilance system which incorporates adverse drug reaction (ADRs) from hospitals and tertiary care centres but not from the community. Involvement of pharmacists in community pharmacy will help in ADR reporting and, monitoring at community level and will help in promoting medication safety in the community. This article describes the community pharmacovigilance program in Nepal and the prospects for community pharmacists.

Key Words

Community Pharmacy; Adverse Drug Reaction; Pharmacist; Nepal

Healthcare system of Nepal: A brief overview

Nepal is a small Himalayan country located in south Asia between China and India with a population of approximately 30 million.¹ Nepal has a low Human Development Index (HDI=138) and a per capita nominal GDP of US\$377 and health expenditure per capita is insufficient to meet the entire cost of Nepalese healthcare expenditure.²

The Ministry of Health of the Government of Nepal is responsible for health policy development, planning and healthcare delivery.³ Healthcare is delivered via tertiary care and specialty centres, regional and zonal hospitals in urban areas and via district hospitals, primary healthcare centres, health posts and sub-health posts in rural areas.⁴ Basic healthcare service and some essential medications are available free of cost through government healthcare structures while citizens have to pay for higher care diagnosis and treatment at both government and private hospitals.

Community pharmacy practice In Nepal

In addition to physicians and paramedics, community pharmacists are key personnel in the Nepalese healthcare delivery system. Community pharmacists are present throughout the country in both rural and urban areas and handle prescriptions, provide symptomatic care and act as a referral service for higher level patient care. As the history of modern pharmacy education is relatively new in Nepal,⁴ most community pharmacies are still managed by people with a basic orientation in pharmacology and medication dispensing. The drug act of Nepal 1978 has recognised these community pharmacists as professional based on their completing qualifications as specified by the Drug Advisory Committee while a person who is a graduate in pharmacy is a qualified pharmacist.⁵ Formal pharmacy education in Nepal started in 1972 with the IPharm (Intermediate in Pharmacy) program from the



Institute of Medicine at Tribhuvan University and BPharm (Bachelor of Pharmacy) from Kathmandu University in 1994.⁴ The majority of pharmacy graduates go to industry, academia and hospital pharmacy⁶ while community pharmacy as a career has been chosen by very few. Thus, there is an acute shortage of pharmacists in the community pharmacy sector. Pharmacists and pharmacy assistants are unwilling to work in community pharmacy due to a perceived lack of motivation, adequate remuneration and appropriate exposure during their training in pharmacy school.⁷ Furthermore, a lack of business; professional knowledge and marketing sense also hamper entry in this sector. Though few in number, pharmacists and pharmacy assistants are embracing their roles in community pharmacies and providing a quality pharmacy service.

Pharmacovigilance and drug safety programs in Nepal

The provision of organised adverse drug reaction surveillance in Nepal began in 2004 through the Department of Drug Administration, the national drug regulatory authority of Nepal, which operates the national pharmacovigilance centre and coordinates regional centres.⁸ Nepal became a full member of the International Pharmacovigilance Program in 2007.⁹ Surveillance infrastructures are in place to report adverse events. For example, hospitals and various tertiary care centres report adverse drug reactions to regional centres, the regional centres report to the national centre and then final reporting is provided to the Uppsala Monitoring Centre in Sweden.⁹ An online database system called *Vigibase Online* is used for online reporting of adverse drug events.¹⁰

The Nepal Drug Act⁵ does not make it mandatory for the pharmaceutical industry to provide safety data from studies conducted in the Nepalese population before the approval of medicines,⁹ thus a systematic and organised pharmacovigilance system is required to ensure appropriate reporting of adverse drug reactions (ADRs) and to facilitate expeditious corrective action. The ADR reports received by regional centres from hospitals and tertiary care centres do not include ADRs due to over-the-counter medication or those from community pharmacies. Community pharmacists have been trained to monitor and report ADRs which has provided a novel source to study patterns of reporting. In a recent study by Subish et al. (2008) using this reporting infrastructure, a total of 71 cases of ADR were reported by 116 community pharmacists, mostly relating to antibiotics/antibacterials.¹¹ The study suggested the need to strengthen the community pharmacovigilance program for safer medication use at the community level.

Similarly, a retrospective analysis from another regional centre reported 113 ADR cases between 2008 and 2011, most

cases were related to antimicrobials/antibiotics.⁹ Further research on systemic adverse drug reactions within this reporting structure found 22 cases of systemic adverse drug reactions and emphasized the need for larger prospective cohort studies.¹²

The role of community pharmacists in preventing drug related problems: An example of diclofenac induced renal impairment

A 56-year-old male presented to the community pharmacy for a regular refill of diclofenac sodium 100mg tablets for his chronic arthritic pain. A verbal interview with the patient by the community pharmacist revealed that he had osteoarthritis and had been taking diclofenac for more than one year. The patient indicated diclofenac was helpful in relieving his joint pain and he had been taking 100mg on a Pro re nata per requirement (PRN) basis. The pharmacist gave him two 100mg diclofenac sodium tablets and, through counselling, convinced him to return to the community pharmacy with his medical report. The patient's medical report confirmed osteoarthritis as well as the patient's use and dosage of diclofenac. He was also offered non-pharmacological therapy which included heat therapy, appropriate exercise after consulting a trained physical therapist and tailored lifestyle measures. The patient followed the non-pharmacological remedies and started taking diclofenac when required. In addition to the medical report, the community pharmacist interviewed the patient to obtain additional details about his medical history. The patient reported that he started feeling better after taking diclofenac and following non-pharmacological management. He was followed up by his orthopaedic doctor on a quarterly basis, and subsequently visited random retail pharmacies in the city for his diclofenac refills. The patient claimed that he was never made aware of the adverse effects of long-term use of diclofenac by his doctor during his visits or by the local retail pharmacist while he presented for a refill.

Further history taking by the community pharmacist showed that the patient was on symptomatic management of osteoarthritis and due to a previous history of a stomach ulcer, he was offered a non-pharmacological remedy by the doctor. The patient took natural Ayurvedic medicine for two years in conjunction with lifestyle changes. The doctor also performed a colonoscopy and treated his gastric ulcer with ranitidine 150mg daily as long-term preventive therapy. During a complete review of systems (ROS) by the community pharmacist, the patient denied any medical complaints, except for mild gastric pain for which he was taking



ranitidine 150mg once daily. He denied any interference in his daily activities, but occasional back pain and joint pain was relieved by 100mg of oral diclofenac. The patient also reported flank pain and slightly foamy urine for the past month for which he did not seek any medical attention. Suspicious of the possibility of renal damage due to chronic diclofenac intake, the pharmacist counselled the patient about the need to rule out any adverse effect or damage to the kidneys due to prolonged diclofenac use. The patient was advised to seek medical care and was referred to a nephrologist. A referral note to the nephrologist about the patient's condition was given to the patient.

The nephrologist did a complete examination and performed a complete laboratory panel for the patient. Results were as follows: erythrocyte sedimentation rate (ESR) of 5mm/h (reference range 0-20), serum creatinine 1.2mg/dl (0.7-1.3), uric acid 25mg/dl (20-45), and white blood cell (WBC) count 5000/cmm (4000-11,000). His body mass index (BMI) was 26.4kg/m.¹³ His creatinine clearance calculation using the Cockcroft and Gault formula is 59.1ml/min which indicated a mild renal impairment.¹⁴ Echocardiography, endoscopy, urine examination and other tests were normal. He was also referred to the orthopaedic doctor. After a general examination, the orthopaedic surgeon informed the community pharmacist and nephrologist that he prescribed acetaminophen 500mg twice daily as a safer analgesic, recommended continuance with the non-pharmacological therapy, prescribed capsicum cream for local application twice daily, and suggested physical therapy with a physiotherapist and a regular meeting for follow-up with the community pharmacist about his medication. He was given a low dose of acetaminophen and was warned about the consequences of liver damage that may occur if the recommended daily dose of acetaminophen was exceeded or when use was unnecessary and prolonged. Two weeks after his last visit with the pharmacist, the patient denied flank pain and his urine was clear. His renal function was returning to near normal, as his serum creatinine was 1.0mg/dl and his creatinine clearance calculated by using Cockcroft and Gault formula was now 70.9ml/min.^{8,14} He regularly used an exercise program at home and had resumed his office work.

Although non-steroid anti-inflammatory drug (NSAID) induced renal damage has long been recognised, many lessons can be learned from this case. It also raises issues in the healthcare system that need to be addressed. Firstly, healthcare practitioners should ask for history of diclofenac use and should avoid its long-term use unless medically justified; if used, its use should be under close and direct medical supervision. Secondly, in this case, the manner in which diclofenac had been used for more than one year in the

patient shows a serious loophole in the collaborative healthcare system, lack of proper communication among healthcare practitioners and lack of pharmaceutical care and patient counselling at community pharmacies. Thirdly, this case also highlights that patients need to be educated about their medications and it should not be assumed that patients are aware just because they have been taking diclofenac for some time. The orthopaedic surgeon, with a simple medication history taking, could have easily discovered the patient was taking 100mg of diclofenac on a PRN basis for the past year. The retail pharmacist also did not take a complete history when the patient presented for refills. These facts illustrate the gaps in the overall healthcare system and the absence of proper medical documentation and communication. These gaps can easily be closed with the service of competent and service-oriented community pharmacists.

Conclusion

Fully qualified pharmacists should be encouraged to join the community pharmacy to change the outlook of the profession and to promote safer medication use in the community. Management of community pharmacies by fully qualified pharmacists will promote safer medicine use, rational drug use and help in preventing drug-related problems. If all professional staff in community pharmacies reported, monitored and were aware of possible adverse drug reactions, they could help in the reduction of potential drug-related problems in the Nepalese community.

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CONFLICTS OF INTEREST

The authors declare that they have no competing interests