Letters to the Editor
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Pharmacovigilance in Nepal: Whose baby is it anyway?

Corresponding Author:
Name: Dr. P. Ravi Shankar
Email: ravi.dr.shankar@gmail.com

Dear Editor,

I read with great interest the brief report by Bhuvan KC and co-workers examining whether community pharmacists in Nepal have a role in adverse drug reaction (ADR) reporting.[1] Having been associated with the pharmacovigilance system in Nepal for a number of years I feel that after the initial days of good performance the system is now beginning to slow down and there are major issues to be addressed.

In Nepal, like in many developing countries, most efforts and endeavours are tied in with personal gains and profit. Pharmacovigilance is increasingly being regarded as something good and useful with which people are reluctant to be involved because of little potential for personal gain. Reporting and working up an ADR requires a lot of effort. Under-reporting is a major problem as evident from a recent study conducted at the regional centre at KIST Medical College, Lalitpur[2] and other reported studies. A major issue is what we can provide back to the health personnel who report ADRs in terms of improved knowledge and skills. Community pharmacies as a major source of healthcare in Nepal can play an important role in reporting ADRs and improving medicine safety if they are committed and motivated and a system for reporting can be initiated. A possible problem can be the time spent on the reporting procedures which can reduce the time for dispensing medicines. Dispensing medicines is a money earning process while pharmacists do not earn money reporting ADRs.

The issue of compensation either in monetary terms or in terms of increased knowledge and skills should be addressed if health professionals are to report ADRs. Greater involvement of the Nepalese pharmaceutical industry in reporting ADRs may be required because, in many developed nations like the United States, the industry accounts for a large percentage of the reported ADRs. Consumer pharmacovigilance could also be a good imitative to reduce under-reporting, promote consumer rights and increase patient knowledge about the adverse effects of medicines.[3] Despite the low literacy level of the Nepalese population, poor economic status and other problems, consumer pharmacovigilance could play an important role in the country and certain postgraduate students have selected this as a topic for their PhD dissertation.

In Nepal at present there is no single organisation responsible for pharmacovigilance. Pharmacovigilance is a part of the activities of the Department of Drug Administration (DDA), the national drug regulatory body. This may be a good thing as the regulator has an important role in ensuring medicine safety. However due to a variety of reasons pharmacovigilance receives lesser priority compared to other functions of the organisation. The same is true of the regional pharmacovigilance centres located in medical schools. Here again pharmacovigilance is only one of the many responsibilities of the associated personnel. At present the system is able to cope because of the low volume of reports. Once the number of reports increases this may be difficult.

A major challenge in Nepal will be in deciding which organisation should take the lead role in pharmacovigilance and whether they will be able to devote sufficient time to this critical activity. Translating knowledge of ADRs into better prescribing and safer use of medicines can be another challenge. Under-reporting and complacency should be overcome. In Nepal a large number of patients obtain treatment from complementary and alternative medicine practitioners and these are an important category of caregivers who should report ADRs. All prescribers in Nepal should be informed about the present status of different drugs in the market with regard to safety and ADRs enabling prescribing and dispensing decisions to be modified taking into consideration the national pharmacovigilance data. I believe this can serve as a powerful stimulus for ADR reporting. Greater involvement of medical and other health professions schools is required considering the recent explosion in their number. The national pharmacovigilance centre has to take the lead to equip schools to effectively promote pharmacovigilance in their institutions and regions.

Sincerely,

Shankar PR

Xavier University School of Medicine, Oranjestad, Aruba, Dutch Caribbean

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Cutaneous manifestations of neonatal sepsis

Corresponding Author:
Name: Joshy M Easow
Email: dr.jmeasow@gmail.com

Dear Editor,

We would like to commend Kali A et al for their diligent work leading to the successful therapeutic outcome as described in their article titled 'Neonatal sepsis and multiple skin abscess in newborn with Down's syndrome: A case report'.[1]

We believe the value of this already unusual report would have been fostered, had they discussed on Ecthyma gangrenosum (EG). EG is an uncommon cutaneous infection associated with bacteraemia due to Pseudomonas aeruginosa, though EG-like lesions have been observed with other bacterial and fungal infections.[2]

Impaired humoral and cellular immunity as seen with Down's patients increases susceptibility to infections. The lesions of EG result from perivascular bacterial invasion of arteries and veins in the dermis and subcutaneous tissues, producing a necrotizing vasculitis.[3] Primary cutaneous lesions of EG initially appear as painless round erythematous macules that rapidly become pustular with surrounding erythema. A haemorrhagic focus appears in the centre, forming a bulla. As the haemorrhagic bulla spreads peripherally, it evolves into a gangrenous ulcer with a central eschar surrounded by an erythematous halo. Perivascular involvement can occur by haematogenous seeding of the skin in bacteraemic patients or by direct inoculation through the skin in nonbacteraemic patients. Skin biopsy for histopathological examination and culture would have ruled out this diagnosis.

Mostly in late onset neonatal sepsis (LOS), the infection is hospital acquired (or care-giving environment), as suggested by the isolation of MDR-ESBL. A Gram stain from the lesion could have been used to initiate appropriate empirical treatment, followed by modifications upon receipt of a culture and sensitivity report, as early initiation of therapy leads to favourable outcome.

Clinical liaison and robust infection control policies augment good healthcare practices, a role to be considered proactively by Clinical Microbiologists of our subcontinent.

Sincerely,

Joshy M Easow
Prasobh K Krishnan
Department of Microbiology, Azeezia Institute of Medical Sciences and Research, Quilon, Kerala, India

Shailesh Kumar
Department of Microbiology, Indira Gandhi Institute of Medical Sciences, Patna, India

Noyal M Joseph
Department of Microbiology, Pondicherry Institute of Medical Sciences, Pondicherry, India

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