CHAPTER: SIX

PROPOSED INTERVENTIONS

Looking into the results of this research and consulting many other studies done with interventions, a collaborative effort through educational, regulatory and managerial interventions would be planned as an interventional strategies for healthcare professionals, community pharmacists and most importantly for consumers [36, 72, 94, 102, 109]. The interventions should be planned appropriately for their easy and feasible implementation. These interventions can be grouped for three groups of population:

6.1 Plan for Healthcare professionals: Follow up with all HCPs

There should be a routine meeting with all the HCPs working in a regional pharmacovigilance centre regarding the reported ADRs for the regular dissemination of the reported ADRs. This would definitely support ADR reporting. There should be continuous medical education (CME) sessions for sharing information about ADRs and to promote ADR reporting. Studies have shown that there is an increased level of knowledge and awareness after the educational intervention for healthcare professional [86, 87]

6.2 Interventions for consumers:

6.2.1 The national pharmacovigilance centre should be informed about the possible importance and advantages for this new initiative for involving consumers in the pharmacovigilance system of Nepal.

6.2.2 The regional pharmacovigilance centres should also be informed about the new initiations and the objectives of this new system of ADR reporting.
6.2.3 An ADR reporting form should be designed on the basis of the survey results among the patients for ADR reporting process.

6.2.5 ADR reporting forms should be developed in the local languages for a better understanding and coverage of the patients.

6.2.6 The ADR reports should be distributed from the common receptions of the hospitals having regional pharmacovigilance centres and should be collected from the patients.

6.2.7 Educational materials should be developed from the national pharmacovigilance centre for raising awareness for the importance of ADR reports from the consumers.

6.2.8 These educational materials for educating patients for ADRs should be made available through the websites of the national and regional pharmacovigilance centres.

6.2.9 Consumer education on drugs safety can be done via a robust collaboration between DDA and the National Health Education Information and Communication Centre (NHEICC). This will definitely help to bring consumer education into action. NHEICC is a centre in the Ministry of Health and Population responsible for an integrated approach and one system for advocacy, community mobilisation, behaviour change communication, and health service programme and promotion activities.

6.3 Training pharmacovigilance staffs (especially pharmacists) for carrying out assessment of ADR reports obtained from consumers. The areas for training could be in data collection forms, coding and interpretation of ADRs, causality and severity assessment scales and possible risks management.
6.3.1 Recording and documentation of data from consumers for any further data mining processes [51].

6.4 Regulatory interventions

1) To formulate a national policy to strengthen ADR reporting and pharmacovigilance in Nepal. Designing a work plan to involve consumers in the existing pharmacovigilance program to complement and strengthen the pharmacovigilance system.

2) Framing guidelines for establishing and setting up a pharmacovigilance centres for HCPs and consumers.

3) To incorporate pharmacovigilance in the curriculum of the Bachelor in Medicine and Bachelor in Surgery (MBBS) during medical graduation programs. Similarly the other HCPs like nursing, pharmacy and other allied professional’s syllabus should also contain curriculum on pharmacovigilance.

4) National Heath Policy, 1991 do not address the ADRs and Pharmacovigilnce. [117], but the new revised policy has some space for these issues which has to be addressed appropriately.

5) Establishment of Pharmacovigilance and consumers’ pharmacovigilance centre: These types of centres should be encouraged for every Individual health care facilities, especially tertiary care facilities hospitals. This can be started in the hospitals with already existed regional pharmacovigilance centres as a pilot project and can be expanded once seem to be feasible after obtaining the feedbacks of the centres.

6.5 Managerial interventions

6.5.1 Drug regulatory authorities
Department of drug administration (DDA) is the national drug regulatory authority which is concerned with all the ADR reports and ADR reporting
process. Also, the DDA is the national drug regulatory authority which is responsible for handling with all the ADR reports from the different regional pharmacovigilance centres and also should be responsible for generation of more ADRs via the regional pharmacovigilance centres.

6.5.2 Pharmaceutical companies

Another important stakeholder for consumer reporting is the pharmaceutical companies. These companies should mandatorily report ADRs. Consumers can also report their ADRs to the pharmaceutical companies.

6.5.3 Organizations for health care professionals and pharmaceutical organizations

It is very important to inform the health care professional organizations like, doctors, nurses, pharmacists and also to the pharmaceutical organizations before initiating consumers pharmacovigilance in any country and also in Nepal. They should be assured that the consumers ADR reports are not there for replacing or arguing any ADR reports made by these HCPs. Consumer reporting should always be welcomed as a complementary resource from other sources.

6.5.4 World Health Organization

The national regulatory authority, and the national pharmacovigilance centre of Nepal, i.e., DDA should report to the international centre for drug monitoring in WHO, Uppsala, Geneva. This information should also be disseminated to all the regional pharmacovigilance centres in Nepal [15].

6.5.6 Regional and the national pharmacovigilance centres

The national pharmacovigilance centre should inform all the regional pharmacovigilance centres about the initiation of the consumers’ pharmacovigilance system and also should organize trainings for better understandings for the subject area.
1.9.5 Consumers organizations, Media and NGOs

The national pharmacovigilance centre should also have to initiate a healthy lead towards establishment of the consumers pharmacovigilance. The DDA can also collaborate with the National Health Education Information and Communication Centre (NHEICC). There should be a vigorous promotion of this new initiation though media and the journalists. General people and the consumers can be made aware for initiation of this new service in Nepal [48].

6.5.8 Organizations for patients

Consumers organizations should be informed and involved in consumers organizations. There should be a formal acceptance for the consumers pharmacovigilance. These organizations can contribute significantly in raising awareness about the ADR reporting and presenting a consumer-oriented method of initiation in a regional and national pharmacovigilance centre. Also the consumer reports should be forwarded and assessed by the national pharmacovigilance centre.