CHAPTER: FIVE

DISCUSSION

Pharmacovigilance has become an important aspect of modern health care system. Monitoring and reporting of adverse drug reactions has become an essential part for the safe use of medicines. Spontaneous reporting has been an important mechanism of for reporting ADRs around the globe. Not many studies are done in Nepal for evaluating and assessing ADRs among the important stakeholders such as healthcare professionals, pharmacists serving in the community settings as a community pharmacists and most importantly among the consumers who consumer medicine regularly for treating their diseases.

This study focuses on initiating pharmacovigilance system in Lalitpur district of Nepal where there is no any system for the consumers to report ADRs. For this, three group of people were studied for assessing the knowledge, attitude and practice of pharmacovigilance and consumers’ pharmacovigilance.

5.1 HEALTHCARE PROFESSIONALS SURVEY

This research done among the healthcare professionals is thought to be the first study done along with the educational intervention. This research has assessed knowledge and attitude for pharmacovigilance and consumers pharmacovigilance as a pre-post educational intervention. As expected, the overall scores for knowledge and attitude has increased significantly after the intervention session. Some differences were being noted among the various subgroups of respondents before and after the educational intervention. The information sharing for ADRs and ADR reporting should be done periodically as a continuous basis. The best platform for discussing and sharing about this matter would be the continuous medical education (CME) sessions. This type of CME sessions should be conducted at least twice a year for the continuous follow-ups and also for the new healthcare professionals who join newly in the institute.
5.1.1 The scores for knowledge

The findings of this study has revealed low scores for knowledge about pharmacovigilance and ADR reporting system among the healthcare professionals. This type of findings resembles with the other researcher’s results [80-83].

Developed countries have a better scenario about the knowledge regarding ADRs and ADR reporting system and processes within the HCPs. A yellow card scheme exists in many medical schools in the United Kingdom which has been incorporated in the undergraduate curriculum for HCPs [84].

Interestingly, the scores for doctors and nurses improved significantly as compared to the other HCPs which was a similar type of observation obtained by a study done among the HCPs in another medical school of Nepal [85].

A genuine reason for the differences among the developed and developing countries may be associated with the course content about the ADRs and pharmacovigilance. Only some medical schools at Nepal has included the ADR related topics and their assessment for the students, whereas other schools still lack the inclusion of this topic in the MBBS curriculum [86]. Not including any topics related to ADRs and their assessment would be an important limitation about the awareness towards the subject among the all HCPs. The situation remains same in the case of curriculum of nurses and other paramedical courses.

There should be a continuous professional education system established for better outcomes about the knowledge regarding ADRs and ADR reporting systems. These type of regular sharing of information can be proven to be beneficial for retaining the information about pharmacovigilance. Trainings should be organized for the HCPs related to pharmacovigilance for enhanced information sharing among the HCPs towards ADR reporting process.

Educational level of the participants also have a positive role towards the knowledge scores. Higher the educational levels has been related with the improved scores after the educational intervention in a study [87]. A study done among the pharmacists has shown improved scores for knowledge and attitude after an educational intervention [88].
5.1.2 The scores for attitude

Both males and females showed an improved scores for attitude after the educational intervention sessions. Participants showed an improved score coming from different ethnic backgrounds. HCPs belonging to Chetri ethnicity has showed a significant improvement in the scores. The reason behind this may be using more resources available for education. There are a variety of ethnic groups in Nepal. These people have a common language and share the traditions and religions. A broad stratification in this group of people sharing many group of people is termed as ‘jatis’ [89].

Attitude can be defined as a way of thinking that affect a person’s activities. It can be taken as an individual's idea for presenting an appropriate behaviour towards using medicines for treating their diseases [89]. Attitudes may be understood as a positive or negative thoughts towards anything. Practice might be improved with a positive and proper attitude and may deteriorate with a negative attitude [90, 91].

There is no any system made for mandatory reporting of ADRs by HCPs in Nepal. Spontaneous reporting is solely dependent voluntarily and depends upon the wish of the HCPs like doctors and nurses. The results has revealed that there is an improvement in the overall scores of doctors and nurses. There have been many evidences of underreporting among the HCPs [66, 85]. There are many reasons cited in the literature for underreporting. Physicians and other healthcare professionals may be busy for treating the disease and giving healthcare to the patients as their top priority. Nursing staffs have shown an improved scores for knowledge. Research from China reveals that nursing staffs can come across to many ADRs as compared to any other HCPs but have not ever reported any ADRs [92]. Nurses are not yet involved in any ADR reporting in Nepal. The number of medical doctors and dentists in Nepal are 10,197 (3.64/10,000 population), nurses and midwifery personnel about 32,846 (11.71 /10,000 population), and 731 (0.261 /10,000 population) are licensed pharmacists [26].
Since, the patient and doctor ratio is not sufficient enough, (3.64/10,000 population), and the professionals find difficulty for sparing enough time for the ADR reporting process. Most of the HCPs mentioned that they were not knowing about the existence and presence of ADR reporting form in the study site and the entire pharmacovigilance system in Nepal. This finding was same as the other studies done among the HCPs [93, 94].

Another limitation for the effectiveness of the intervention was its short duration of educational intervention. Since, the intervention carried out was for a short duration and may not be sufficient for showing better improvement in participants’ knowledge and attitude scores. The intervention session was carried out for two hours and there was no any repetitions done. The retention for the information shared about the ADRs and Pharmacovigilance was also not checked. There was no any system for disseminating the information sharing from the regional pharmacovigilance centres for providing feedback to the HCPs. The same questionnaire was used immediately after the educational intervention for evaluating the knowledge and attitude. Information about the scores or retention were not evaluated.

5.2 COMMUNITY PHARMACISTS SURVEY

5.2.1 Total scores for KAP

Total scores for KAP were found to be improved for males and females both after the intervention. Similarly the scores were improved when compared to pre intervention and retention scores. The information were retained when assessed for females after the educational intervention.

None of the participants had received any training for ADR reporting and pharmacovigilance in the past. The scores for the age group 21-30 and 31-40 years community pharmacists were found to be significantly improved after educational intervention and also when compared to pre and retention scores.
This was similar to a study done in Malaysia for the community pharmacists where the scores after the intervention got improved in the participants with the mean age of 33 years [95].

Similarly, the participants having experience < 5 years, 5-10 years and > 10 years were having improvement in the scores after the educational intervention but the retention scores were not significant. The total scores for the pharmacists with patients number less than 50 and 50-100 were improved significantly after the intervention but could not get retained for long. Area wise observation concluded that the total scores for KAP improved significantly for rural and urban pharmacists without any significant retention. The pharmacists having diploma level of educational qualification were found to have an improvement in the total scores. Pharmacists working with the number of medicines in between 20-40 and less than 20 were also found to have significant improvement in scores after the intervention and for the retention scores. The pharmacists consulting the reference books as CIIMS and NDR were having better and significantly improved. Likewise, the scores for the dispensers one, two and three were improved significantly after intervention but none of the number of dispensers could retain the shared information for long time.

Almost half of the participants were having diploma level of education, followed by CMAs whereas minority of people were having bachelor and masters degree as their educational qualification. CMAs are community medicine auxiliaries, who undergoes basic medical training for 18 months after the completion of their basic schooling of 10 years. These people are trained for diagnosing and managing the common types of diseases which is present at the local places in Nepal and can also refer the patients to the other specialized health care service stations for specialized care if required [26]. Diploma level of pharmacy education is being provided by various colleges which gets a formal affiliation from the council for technical education and vocational training (CTEVT). The diploma in pharmacy is a three year program after the basic schooling of 10 years in Nepal. This is also called as School Leaving
Certificate (SLC), which is a government board. The Diploma in pharmacy program prepares a pharmacy assistant as a middle level of service provider in pharmaceutical sector. This program prepares a good number of human resource for being a media in hospitals and community settings for providing the pharmaceutical care in both the rural and urban settings. The reason of being diploma pharmacy assistants in the community pharmacy settings can be the easy availability of these people in our settings as a supporting paramedical staff. Also the drug regulatory authority in Nepal, i.e., DDA has some mandate for involving some pharmacy human resource for registration of a new pharmacy shop in the community settings [96, 97].

5.2.2 Knowledge scores for pre intervention, post intervention and retention

The scores for knowledge improved after educational intervention for both genders but males showed a better retention effect as compared to female participants. The age group of participants below 20 years to 40 years of age showed a significant improvement for knowledge scores after intervention but the retention scores were better seen for only 21-30 years respondents. There was an improvement in scores after intervention for the respondents having working experience less than 5 years and 5-10 years. This group of people have shown a better retention for the shared information too. Similarly, the community pharmacists having patient number less than 50 and 50-100 showed a significant improvement in post intervention and retention scores as compared to the pharmacists having more than 100 patients per day at the community pharmacies. Pharmacists working in rural and urban areas showed a significant improvement in the scores after intervention but the rural respondents had better retained the information than the urban participants. Similarly, the results have revealed that the participants having diploma level of educational qualification has shown an significant improvement for the knowledge scores but the respondents having only an orientation level of educational qualification were seen to better retain the information shared even after one and half months for retention. Likewise, looking at the scores for the pharmacists having number of medicines 20-40 and more than 40 have an
improved scores seen as statistically significant. Pharmacists consulting books as a reference for CIIMS and NDR were shown to have a significant improvement in the scores for knowledge but the pharmacists consulting CIIMS as a reference book showed a better retention for the information shared even after one and half months after the educational intervention. Lastly as per the scores after intervention, the pharmacists having two dispensers showed an improved scores after the intervention whereas, the pharmacists using four dispensers had relatively better retention than others.

The total knowledge scores for the participants was found to be increased in a similar type of study done in Malaysia and Iran in the year 2011 [95, 98].

5.2.3 Attitude scores for pre intervention, post intervention and retention
Females showed an improved scores after the intervention, whereas both the gender had significantly retained the shared information during the educational intervention. All the age group of respondent pharmacists showed an improvement in the attitude scores but not significantly. But the respondents from below 20 years to 40 years of age group had a significant scores after the assessment for retention. Pharmacists dealing with the number of patients below 50-100 showed a significant improvement after the intervention and retention. Similarly, the results showed that the pharmacists having experience 5-10 years and more than 10 years a better score after the intervention and retention as compared to the respondents having less experience. Likewise, the pharmacists coming from rural areas showed significant improvement after the retention but both the rural and urban pharmacists showed better retention scores for attitude. The scores improved for the participants having various educational levels but only the pharmacists having diploma level of education showed significant improvement in the attitude scores. Respondents having the number of medicines 20-40 showed an improved score after the intervention whereas the number 20-40 and >40 had showed a better retention scores. Regarding the consultation with the CIIMS as a reference book, the scores got
improved after the intervention, whereas, the pharmacists consulting both CIMS and NDR as reference sowed a better retention scores. Pharmacists having three dispensers showed a better score after the intervention and the number of dispensers two, three and four has shown a better retention scores as compared to others.

5.2.4 Practice scores for pre intervention, post intervention and retention

The scores for practice seemed to be significantly improved after the educational intervention and even after the retention for both males and females. The age group scores showed that the pharmacists from the age below 20 years, 21-30 years and 31to 40 years has shown an improved scores for practice after the intervention and the retention. Similarly, for all the pharmacists having working experience from less than 5 years to more than 10 years showed a significant improvement of scores after the intervention as well as after the retention assessment. Similarly, the patient number less than 50 showed a better score after intervention and the patient number less than 50 and 50 -100 has shown better retention scores for practice. Both the rural and urban pharmacists showed significant improvement for practice scores after the intervention and after the retention. Pharmacists with a diploma level of education had an improved score after intervention whereas, respondents with diploma level of education and CMAs showed a better retention scores. Number of medicines 20-40 and more than 40 has showed a better scores for both after intervention and after the retention. Similarly, the books used for reference as CIIMS, NDR and both the books showed a significant improvement in the practice scores. Likewise, the number of dispensers one, two and four showed better scores after intervention whereas the number of dispensers one, two, three and four showed better retention for the practice scores.
ADRs have a major role towards morbidity and mortality in any healthcare systems. ADRs are also connected with the penalties in terms of money [15, 99]. Pharmacovigilance has been already established in many countries. Countries are advocated for establishment of their own pharmacovigilance centres due to many differences among the individuals in many aspects like variations in genetic make ups, variations in responses towards drug uses, drug regulations policies, drug use patterns and many other factors [100]. Involving community pharmacists has always being proven to be beneficial for reporting ADRs. Since, Nepal is a developing country, where there are many community pharmacy outlets which serve as a first contact for the patients to seek any medical advice. So, community pharmacists can be considered as an important stakeholder in the arena of pharmacovigilance.

This type of educational intervention with retention assessment for community pharmacists is the first study of this type to assess the community pharmacists knowledge, attitude and practice towards pharmacovigilance and consumers pharmacovigilance in a developing country like Nepal. There are many studies to highlight the poor knowledge and attitude about the ADR reporting mechanism for the community pharmacists who do work in a community settings [101-105].

Various studies from several countries has stated that pharmacists working in community settings do lack adequate knowledge about ADR reporting. This is very similar for our research results. Studies have mentioned that the reporting of ADRs is seen from 3% to 14.7% [106]. Our study has shown that most of the pharmacists did not know to report ADRs to the national pharmacovigilance centre DDA. This was again similar to the study done in Saudi Arabia where there was very low awareness regarding the ADR reporting process. [106] pharmacists can make many important changes if properly known or trained about the existing process of ADRs. Studies done in different parts of world has shown about the significant contribution towards strengthening pharmacovigilance and ADR reporting [107-109]
Similar to the Saudi research findings, our pharmacists were unaware that DDA was the national pharmacovigilance centre for reporting ADRs [106]. There is no any legal document from DDA mentioning that the community pharmacists can also report ADRs. Lack of awareness and also the lack of advertising by DDA for community pharmacists and consumers for reporting ADRs is one of the major limitation for their involvement in reporting process of ADRs. Interacting with the community pharmacists in a periodical basis would help to disseminate the information regarding the collecting and reporting ADRs. DDA should take initiatives for doing such kind of gathering for community pharmacists for disseminating the required information about the ADR reporting process. Educational intervention has shown an improved scores for knowledge, attitude, practice and even with the total scores in our findings. This type of improvement has been supported by various other studies, where the mean scores changed after intervention program. [72, 93, 102, 109]

ADR reporting rate is seen better among the pharmacists who have received any continuous training program like continuous pharmaceutical development programs. Studies have proven improvements in ADR reporting process for the pharmacists who have attended this type of training programs for ten hours per year [72, 93, 102, 109]. The post intervention results is similar to our research findings where the scores have improved for ADR reporting but the retention scores were not very significant, which indicates that such type of educational intervention should be organized periodically and should be repeated frequently to assure better retention for making pharmacists more liable towards ADR reporting. This type of result was seen in similar types of studies where the training programs showed a positive and better response for enhancing knowledge and improving attitudes for ADR reporting process [58]. The knowledge scores before intervention was seen to be less which has been seen to be similar with the other studies being done in other places [96, 100].

The practice scores has been improved after the intervention session for the variables like age and length of working experience which is very similar to the studies done previously. [98, 100]
About 46% of community pharmacists working in community levels were unaware of ADR reporting systems in Nepal. This was very similar to the studies done by a study in Iran and China. The major reasons for not knowing about the existence of the ADR reporting system existing in Nepal is not properly being publicized and many people are still unaware about this system. Various other studies also suggest that people don’t know how and whom to report these reactions after their occurrences [83, 110-114].

5.2.5 Some important queries from participants during the intervention session

There were some queries like about reporting any new types of ADRs which has not been reported till now for the existing medicines in the market, any ADRs to the new products and any ADRs due to herbal preparations. The same types of queries were seen in a study done in Iran. There are many other studies which has highlighted about reporting for these types of reactions [110, 114]. Studies have also proven that all types of ADRs should be reported than only being focused to serious and life threatening ADRs [115].

The Crosstab p value for question numbers with gender, age and education of the respondents showed that there was a significant differences in the questions like Adverse drug reactions are one of the major causes of death in the world, the most preferred method for ADR reporting, location of the centre for ADR monitoring and reporting, DDA.

5.3 Consumers Survey

Consumers involvement in the current context of ADR reporting system is always thought to be beneficial for by and large all individuals who consume medicines. Consumers should be involved in ADR reporting process as an important stakeholders. This has already being shown in the figure 2.1 from a report from SIAPS. Encouraging consumers reporting is a vital step which can further strengthen the pharmacovigilance system. Studies has proven the beneficial roles of consumers involvement [54, 116]. In a developing country
like Nepal, consumers may be an important group of people for improving the current status of pharmacovigilance.

Many people using medicines are still unclear about the real understanding of ADRs in our study. Only 53.5% of patients had an understanding about the meanings of ADRs. This was in accordance to the research done in a hospital of Ireland, where 30% of patients who were on warfarin could better respond about the risk of bleeding as one of the important ADRs [64].

This low awareness of the general public can be improved by measures like conducting an awareness program and medicine use campaigns as suggested by a research done in the Beaumont hospital in Ireland [64]. However, many consumers agreed significantly that the purpose of adverse drug reaction reporting was to use safe drugs. This reflected that people were having a better understanding about ADRs and hence a better cognition about drug safety. A research done in Dublin has showed that the patients are mostly unaware and inaccurate about the risks associated with their medicines [64]. Very few consumers (2.54%) were known that DDA is the national pharmacovigilance centre developed in Nepal for collecting and evaluating ADRs. The reason for this low awareness about the pharmacovigilance centres may be less programs for patient’s awareness for negative effects like ADRs caused by using medicines. There are only eight regional pharmacovigilance centres in Nepal, among which, many are situated in the capital city Kathmandu only. People are not aware that there is an existence of a pharmacovigilance program. One of the reasons may be that no any legal document or any act related to drugs contained the term ‘pharmacovigilance’ earlier, but now, a revised and a new edition of the health policy contains some terms and operable definitions of ADRs [117]. Apart this, till date there is no any involvement of consumers in ADR reporting process and it has been solely dependent upon the healthcare professionals [34].
The educational level was directly correlated with the statement for the purpose of ADR reporting process. The variable of education was related with the safe use of medicines. This was similar to a study done in China which was done for evaluating the awareness of ADRs and pharmacovigilance among the healthcare professionals. The results of this study done in china showed that the respondents with a higher level of education were having a greater level of knowledge and awareness about ADRs [118].

There was a significant difference noted for the statement for how one can obtain information about ADRs with regard to age. A study done in Sri Lanka regarding the general people’s awareness about the mass treatment regimen for filariasis has revealed that there was no any significant association with the living areas of the participants and their tendencies to report any experience of ADRs [119].

About 91.8% of consumers accepted that ADR reporting system should be beneficial for consumers. This is well proven that involving consumers will bring many advantages and benefits to the existing pharmacovigilance systems everywhere in the world. Participation of consumers in ADR reporting systems can also overcome the problem of underreporting of ADRs by healthcare professionals [40, 58]. Researchers have found that even a lay person can report about the ADRs and is very important for assuring safe use of medicines [120].

Participants with masters level of education and with diploma level of education has shown to have a better scores for knowledge and total scores for knowledge, attitude and practice. This result confirms that masters level of education have better awareness and perceptions towards ADR reporting. The consumers having diploma level of education were also showing better perceptions for the ADR reporting areas. This might be due to their own experience about suffering from ADRs. There should be maximum programs...
Thirteen consumers (8.3%) emphasized that “Information about medicines can help to manage promptly for the adverse drug reactions in neighbours.” This response from consumers is also in accordance to a study done by researchers in 2009. This study has also focused on educating consumers for reporting ADRs and the process for reporting ADRs [120]. In a developing country like Nepal, where consumers find the community pharmacies as their first point of contact, it is very vital to organize an educational awareness program for both the consumers and community pharmacists to avoid the incidence of self-medication and other drug use problems. These drug use problems might also be an important cause for ADRs [43]. Besides, consumers also have their right to know about the medicines. They have a right to get right information about their medicines [48]. In this way, consumers right will also be strengthened. These efforts will definitely protect other patients from being affected with the same types of sufferings due to the ADRs [120].

13.8% of consumers in our study stated that “proper knowledge helps for appropriate utilization of the medicines.” This is very essential for a country to strengthen the existing system for pharmacovigilance. Looking into many programs in various other developed countries for encouraging consumers to report ADRs. They boost the consumers’ participations in the existing pharmacovigilance program. Thus, the patients’ health rights are also being promoted [48].

Our results has shown no any significant difference to questions and statements between the variables like gender, age and education.

Almost sixty percent of patients said that they are being not informed about any ADRs which might occur after taking medicines and also many of them opined that they would prefer visiting a doctor for reporting any ADR by
verbal method of reporting ADRs. These methods will increase the awareness for the possible risks for getting any ADRs and thus the morbidity and mortality rates due to ADRs would be reduced [64].

Thirty four percent of people have agreed and stated that there should be an establishment of some centres particularly for consumers for obtaining authentic information regarding ADRs along with the management part. Many respondents agreed that there should be an establishment of a pharmacovigilance centre not only at the study site, i.e., KIST Medical College, but also at each and every hospital in the country for the possible benefits for the consumers.

5.3.1 Designing an ADR reporting form for consumers [51]
There should be many factors considered before designing an ADR form for consumers. The various factors are mentioned here after getting the results from about 50 consumers from the Imadol area where the hospital is situated.

5.3.2 Language of the ADR form
Regarding the designing of ADR reporting form for consumers, about 39 patients agreed that the form should be developed in Nepali language for better understanding of the form. This is self-explanatory, as not all the consumers in Nepal are literate. Though, the Lalitpur city has been claimed to be 100% literate, but even the patients coming from rural areas might not be aware of the English language and cannot understand the technical terms. This has many similarities with a study done by Mohamed et al in Malaysia [48, 67]. In fact, the ADR reporting form should be designed in all the local languages to promote and encourage each and every individual belonging to different ethnic backgrounds to open up for their sufferings due to ADRs and to prevent others from the same types of sufferings.
5.3.3 Brief identification of the patient or consumer
There should be a small identification of the consumer in the ADR reporting form. Patients’ initials could be a better option followed by a medical history and diagnosis part for understanding the causative/suspected medicines for the disease. In addition to this, the age of the patient, gender, place of residence, and ethnicity can be an additional source of information about the ADRs in particular group of people. There should be an assurance for assuring that the obtained data from the patients will be used for the scientific/study purposes only.

5.3.4 Information on ADR
A detail of the ADR should be present. The details on the type, severity and affected area/organ should be there. This was an important part of an ADR reporting form.

5.3.5 Causative/Suspected medicines
There should be an information on the causative medicine, its dose, dosage form, generic and brand names. Similarly, the expiry date, manufacturing date and batch number is also important. Additionally, the information about the drug manufacturing company should also be there.

5.3.6 Concurrent disease/medicines
This part is an important information about the ADR causing drugs as patients or consumers can easily differentiate the suspected new medicines added to their lifelong medications for certain diseases if used concurrently.

5.3.7 Possible risks
Consumers should be give space for their current and past diseases along with any known allergies to any medicines.
5.3.8 Place/shop for obtaining medicine

There should be some details on place of obtaining medicines. Patients can go there for obtaining more information about the medicines they have bought for any disease. Respondents opined that there should be space given to the possible options for purchasing the suspected medicines like, hospital, local pharmacy or any other place.

5.3.9 Method for obtaining medicine

There should be a space to know whether the consumers obtained the medicine through a prescription or without any consultation with any HCPs and as a self-medication. This information would be really helpful as self-medication is quite common in our part and the patients may be prone towards developing an ADR.

5.4 Information about the reporter for ADRs

The name, address and contact number of the person who reports an ADR is quite essential for further follow ups towards any ADRs. Mostly, the consumers are only the reporters for the ADRs that they may suffer from, but sometimes, somebody else can also report ADRs.

5.5 Ways and means for reporting ADR

There are many ways by which consumers can report ADRs. The countries where consumer reporting has already being established uses telephones, mobiles, fax or emails through the internet. Choice of reporting can be particular for any individual country. In a developing country like Nepal, where literacy levels are not upto the mark, retail pharmacies and other registered pharmacy outlets can also be considered as one of the important area for taking initiatives through placing the ADR reporting forms for consumers. Local pharmacy outlets is one of the site where patients prefer going first to seek any medical attention. Our survey with the consumers from

Initiating Consumers Pharmacovigilance in Lalitpur District
Imadol area also showed the telephonic reporting as the preferred method for consumers reporting.

5.6 LIMITATIONS AND STRENGTHS OF THE STUDY

Limitations of the study

1. The major limitation for the HCPs was for the small duration which may not have been sufficient for significant improvement among the respondents overall scores for knowledge and attitude.

2. The educational intervention session was conducted only once for two hours and was not repeated.

3. The time gap was very less for assessing knowledge and attitudes of the HCPs. It was done immediately the educational intervention session.

4. The effect of the intervention on retention of information was not assessed. The effect of the retention could have been assessed for better output for the HCPs for the scores for knowledge and attitude.

5. There was no any dissemination for the information sharing system for HCPs pharmacovigilance centres

6. Lack of continuous feedback and information sharing by the regional pharmacovigilance centre from where HCPs can obtain information and knowledge about ADRs and reporting of ADRs may be another limitation that could have influenced underreporting of ADRs.

7. Impossibility to include all the relevant healthcare professionals in the study. Also, not all the participants who could be contacted for the pre-test process and some HCPs, particularly nurses, were unable to take time out
of their busy schedules despite our best efforts to create convenient time slots for conducting the study.

8. This study has a small sample size for the community pharmacists from the Lalitpur district.

9. A short time gap of six weeks was taken for the all the study groups like pre, post and retention for community pharmacists’ interventions participants’ retention assessment.

10. The effects of retention could not retain after 6 weeks of time gap which confirmed the fading of the effect of the shared information with time.

11. The sample size for ADR reporting form was only 50. This was a small sample size to get the information about the ADR reporting form from consumers.

**Strengths of this study**

In spite of these limitations, this study is one of the pioneer type in the field of pharmacovigilance. The results obtained out from this study has revealed that HCPs have a very positive attitude for initiation of the consumers pharmacovigilance system in Nepal. The three groups of population taken for this study can be considered as an important stakeholder in this new and noble initiation of the consumers pharmacovigilance system in a developing country like Nepal. The proposed intervention in this research would be a great support for the establishment of consumers pharmacovigilance to strengthen and complement the pharmacovigilance system in Nepal.