CHAPTER: ONE

INTRODUCTION

1.1 INTRODUCTION

Medicines form a major component of modern health care and can be considered as a ‘double edged sword’ having both beneficial as well as harmful effects on human beings. One of the important hazardous effects of using medicines is adverse drug reactions (ADRs) which can be mild, moderate or severe. ADRs can cause various types of disabilities, sickness and even death. ADRs are often preventable if proper measures are taken.

The World Health Organization (1972) defines an ADR as ‘any response to a drug that is noxious and unintended, and that occurs at doses used in humans for prophylaxis, diagnosis, or therapy, excluding failure to accomplish the intended purpose’ [1]. WHO has widened ADRs to include reactions to herbal, traditional and complementary medicines, biologicals, medical devices and vaccines [2].

Adverse drug reactions are considered as an important cause of significant morbidity and mortality worldwide. These reactions have caused a significant number of hospital admissions, ranging from 0.3% to 11% [1]. An ADR should be distinguished from an adverse drug event (ADE). An Adverse Drug Event (ADE) is any unwanted medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment [3].

A commonly quoted meta-analysis performed in the United States indicated that ADRs were between the 4th and 6th most common cause of death in 1997 [4], and approximately, 6.5% of hospital admissions were considered to be due to adverse drug reactions. [5] Hospital admissions due to adverse drug reactions in India account for about 6.7% of admissions and this figure ranges between 0.2-21.7 percent worldwide. [6, 7] A study from Nepal indicates the

Initiating Consumers Pharmacovigilance in Lalitpur District
hospital admissions related to adverse drug reactions was 0.64% [8]. ADRs accounted for 300,000 admissions per year in the United States, and accounted for 6.5% of total hospital admissions [9]. There has been only limited number of studies regarding prevalence of ADRs in developing countries. A study from Iran has found that 11.8% of patients had experienced at least one ADR [10]. Similarly, another Iranian study revealed that approximately 16.8% of patients had at least one ADR and 2.9% of the ADRs were described as ‘lethal’ [11]. A prevalence of 9.8% of ADRs was seen in South India. This study was done over a nine month period in a government hospital of South India by clinical pharmacists. One hundred and eighty seven adverse events were noted during the study. The incidence was found to be 9.8%. Patients had reported the adverse reactions which were confirmed clinically. About 3.4% of ADRs were seen due to ADR related hospital admissions whereas about 3.7% of ADRs were seen during the patient’s stay at hospitals [12]. In the Nepalese context, the prevalence of ADRs was 0.86%, the male to female ratio was 0.85, and 10.81% of the ADRs were considered ‘severe’ [5].

A study carried out in five different hospitals of Kathmandu valley, Nepal found the prevalence of ADR to be 0.86% and the male to female ratio was 0.85. Majority of patients (54.1%) were females followed by male patients who were 45.9%. Skin was found to be the most affected organ and anti-infective were the class of drugs causing maximum number of ADRs followed by IV urograffin (a contrast media) [5]. The study was done over a 5 month period.

The studies quoted above highlights the importance of proper management of ADRs for reducing suffering due to possible adverse effects. Better knowledge about ADRs can save patients’ life and reduce further suffering [12]. ADRs can be an important threat to the health of the people of Nepal as a variety of medicines like allopathic, traditional, homeopathic and ayurvedic are available in the market with their number increasing constantly. The concerned people and institutions should be mandated to report all ADRs, but unfortunately ADR reporting is not mandatory in Nepal [13].
1.2 HISTORY OF PHARMACOVIGILANCE

Pharmacovigilance increased in importance following the disaster caused by the drug thalidomide, which caused the birth of many babies with phocomelia. The disaster provided a major impetus to PV and ADR monitoring. Thalidomide was used as a drug used to treat morning sickness during pregnancy. WHO started the international drug safety program monitoring program in the 1960s [14]. Pharmacovigilance is now established in most countries.

Sub-acute myelo-optic neuropathy (SMON) syndrome was caused by clinoquinol in 1969, and the event of venous thromboembolism was seen due to oral contraceptives. Practolol induced oculomucocutaneous syndrome and blood dyscrasias and gastro intestinal bleeding due to the use of NSAIDs were other important events associated with pharmacovigilance [15]. These reactions influenced the growth of pharmacovigilance.

1.3 DEFINITION OF PHARMACOVIGILANCE

Pharmacovigilance is the “science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug related problems” [16]. Pharmacovigilance plays an important role in rational use of medicines by providing information about ADRs in the general population [16]. Drugs are first tested in animals and later undergo testing in humans termed as ‘clinical trials’. These trials are conducted only in a limited number of people, and women and children are often excluded. Thus, by the time a drug reaches the market its adverse effects in certain sections of the population, like pregnant and lactating women and children, and uncommon adverse effects in normal populations, may not be completely known. Hence even after a drug is marketed, it continues to be monitored for ADRs for a number of years (often called post-marketing surveillance or phase IV trial). This provides information on its use in normal populations under a wide range of conditions [16]. The importance of drug safety monitoring has been acknowledged worldwide and initiatives in safety monitoring of medicines
have been undertaken in many countries. The WHO drug safety program was established in 1968 as a pilot project and now about 104 countries are members of this program.

In specific countries there are different authorities involved in pharmacovigilance and drug safety monitoring. In the United Kingdom, the Medicine Control Agency (MCA) and the Committee on Safety of Medicine (CSM) was set up in 1960. There are many other drug safety programs like, Vaccines Adverse Event Reporting System (VAERS), established in 1990 in the USA in addition to the Medwatch program of the United States Food and Drug Administration (US FDA). In Australia, there is an Adverse Drug Reactions Advisory Committee (ADRAC). Similarly, in Canada, there is the Canadian adverse Drug Reaction Monitoring program [16].

1.4 BACKGROUND ABOUT THE COUNTRY AND DISTRICT

Nepal is a small and landlocked country in South East Asia having an area of 147,181 square kilometres. Nepal is known as the land of Mount Everest, the highest mountain on earth, as the birthplace of Lord Buddha and Goddess Janaki. The country lies between the two economic giants India and China. The total population of Nepal in 2010 was 30 million [17]. The GDP per capita was US$ 735 for Nepali people and the GDP in Purchasing Power Parity (PPP) terms was 1268 US$. [18] The population below 15 years of age was 37 percent and above 60 years was 6 percent of the total population [18]. Urban population was 17.7 percent of the total population [19]. Adult literacy rate was 65.9 percent. [17] For administrative convenience, the county has been divided into five regions- Eastern, Central, Western, Mid-Western and Far Western regions [20].
Nepal has been divided into three ecological regions Figure 1.2. The mountains are seen in the north and cover 35% of the land area. The altitude of these mountains is within a range of 4877 to 8848 meters as seen in Mount Everest, the tallest mountain in the world. Figure 1.2 shows the central hilly region which covers 42% of land area. The altitude of these hilly areas ranges from 610 to 4876 meters. Kathmandu valley which consists of three districts lies in this region. The study site, Lalitpur district is one of the districts of the Kathmandu valley, which also lies in this region.

The last region of the figure shows the flat regions known as ‘Terai’. This area covers about 23% of the whole area of Nepal. This area borders India. The population of the Terai region is about 48% of the country’s population [20, 21].
These regions include a total of 14 zones with 75 districts and 3915 village development committees (VDCs) and 158 municipalities. A VDC is the minutest unit of the Ministry of Federal Affairs and Local Development. There are many VDCs in a district similar to Municipalities. There are 3,625 VDCs currently in Nepal. On an average, there are nine wards in a district. The border areas share an open border area with India. The main aim of these VDCs is for bring together people at the community level for proper use and distribution of funds allocated for a particular village and has a strong influence on the overall development of the village area. The national language is Nepali, but there are many other languages which are being used by people belonging to various ethnic groups [21].

Nepal has a multi-party democracy system from 1990 onwards. Political instability has been a major problem in Nepal. There is no any constitution
formed till now. In spite of many difficulties, Nepal has been able to meet some of the Millennium Development Goals (MDG) [22].

**Lalitpur district**

**Figure 1.3. Location of Lalitpur district inside Nepal**

Lalitpur is one of the three districts of the Kathmandu valley. It is a famous historical city situated in the south-eastern part of the Kathmandu valley. Lalitpur is very famous for cultural traditions, particularly for arts and crafts. This place is also known for carving of stones and making metallic statues. The population as per the 2011 population census was found to be 2,26,728 in 54,748 households. There are many schools and institutes for higher education in Lalitpur district. The study area in this research was situated in Lalitpur district [23].

### 1.5 HEALTHCARE IN NEPAL
Figure 1.4 Organizational structure of Department of Health Services in Nepal.

Figure 1b.1

Initiating Consumers Pharmacovigilance in Lalitpur District
The ministry has three departments namely Department of Health Services (DoHS), Department of Drug Administration (DDA) and Department of Ayurveda. MoHP deliver preventive, promotional and curative health services through DoHS which deliver its services to public through its organizational structure. The network ensures that the health services delivered by the government of Nepal are received by majority of population in places accessible to them.

**Fig.1.5 Public health facilities in Nepal**

The healthcare delivery has been shown in figure 1.5 and 1.6 is for Curative and preventive health services are provided by the MoHP through the organizational structure. The Sub Health Posts (SHP) is the first point for provision of basic health care services. However, the SHP gets patients referred by Female Community Health Volunteers (FCHVs) as well as from venues for community based activities such as Primary Health Care (PHC) outreach clinics and Expanded Programme on immunization (EPI) clinics. Every level above the SHP is a referral point in the network from SHP to Health Posts (HP) to Primary Health Care Centres (PHCC) and to District,
zonal & regional hospitals and at the top of the hierarchy are the tertiary care hospitals in Nepal’s capital, Kathmandu. These all units are run by trained health workers (e.g. Auxiliary health workers (AHW), Auxiliary Nursing midwives (ANM), Community Health Workers (CHW), with medical doctors and nursing staff stationed at PHCC and other higher level specialized medical centres or hospitals. Additionally, medical services provided by private hospitals (Nursing homes), private teaching hospitals, private clinics and missionary hospitals run by licensed medical practitioners' complements and supports the government services. Traditional medicines mainly Ayurveda also is provided to a significant proportion of population in Nepal. Community, district and zonal level Ayurveda centres and hospitals are also managed by MoHP through the Department of Ayurveda [24-26]. The health facilities shown in the fig. 1.5 are in many colours. There are many opportunities for pharmacists to get engaged in these health care facilities. There should be proper government policies for involving pharmacists as a member in an integrated healthcare team.

Fig.1.6 Number of registered pharmacy outlets in Nepal
Fig. 1.6 shows the various registered pharmacy outlets in Nepal. There are many outlets of pharmacies in the community. This area is still not properly developed and has many more possibilities to be explored by the pharmacists.

### 1.6 DRUG REGULATION IN NEPAL

The Department of Drug Administration (DDA) is the national drug regulatory authority of Nepal. DDA regulates various processes like manufacturing, importing, exporting, procurement, and sales in Nepal. Drug manufacturing companies require permission from the DDA to manufacture medicines in the country. Medicines produced in countries other than Nepal have to be registered with DDA by submitting the necessary documents of safety, efficacy and cost. Nepal’s Drug Act of 1978 and National Drug Policy (NDP) of 1995 address elements of medicine safety and public health [27].

The health status of Nepal needs improvement. This can be understood by the low life expectancy, (64 years), high infant mortality rate of 48/1000 live births and maternal mortality rate of 281/100,000 live births. [28] There is no system of health insurance and the country has a shortage of specialized and super specialized hospitals. Nepal is ranked at 157th out of 187 countries in Human Development Index (HDI) [26].

The country produces a significant number of medical doctors every year but very few medical graduates stay back in the country as they get better opportunities in developed countries. A similar situation exists for other healthcare professionals like dentists, pharmacists and nursing staffs. The brain drain has resulted in a very poor doctor patient and other health care professional patient ratio. There are 10,197 (3.64 /10,000 population) medical and dental doctors, 32,846 (11.71 /10,000 population) nursing and midwifery personnel and 731 (0.261 /10,000 population) licensed pharmacists in Nepal.
This low ratio of health care practitioners (HCP) to patients causes difficulty for HCPs to spare more time for ADR reporting [29].

The annual drug consumption in Nepal is 3719.3 million Nepalese rupees [38.7 USD, Conversion rate is 1 USD=101 NRS] approximately, and only about 42% of drugs were being manufactured domestically in 2010. Rest 60% of drugs are being imported from India and other countries [30]. There are about 81 licensed pharmaceutical manufacturers in Nepal 41 manufacturers produce modern medicine, 3 of them are producing veterinary products and 37 of them produce herbal medicines [31].

1.7 PHARMACOVIGILANCE ACTIVITIES IN NEPAL

Nepal’s Department of Drug Administration (DDA) within the Ministry of Health and Population was established as per the Drug Act of 1978. DDA regulates the manufacture, import/export, sales, distribution, and storage of drugs in Nepal and also houses the National Centre for Pharmacovigilance, established in 2004 [27]. Nepal became a member of the International Pharmacovigilance Program in 2007 [32]. There are seven regional pharmacovigilance centres at present in Nepal reporting ADRs to the national centre, which sends reports to the Uppsala Monitoring Centre in Sweden, a centre for international service and scientific research towards patient safety [13]. KIST Medical College joined the programme as a regional centre from July 2008 [33].

1.8 STRENGTHS AND LIMITATIONS OF THE NATIONAL PHARMACOVIGILANCE PROGRAM

Nepal became a member of the International Pharmacovigilance Programme in 2007 [33]. Establishment of a pharmacovigilance program in Nepal signifies the nation’s commitment towards patient care and safety. The national centre and associated regional centres have been continuously active in strengthening...
pharmacovigilance activities. Nepal being a developing country has to overcome many hurdles and obstacles to develop a strong pharmacovigilance program. There are many limiting factors like lack of full-time dedicated staff responsible for pharmacovigilance activities, public awareness programs, and standard guidelines for pharmacovigilance, which may be responsible for causing underreporting of ADRs [13]. One of the most important limitations of the existing pharmacovigilance program in Nepal is lack of dedicated human resources responsible for managing the pharmacovigilance programs in the regional centres and the national centre [13]. Till date, there is also only one person in the national pharmacovigilance centre to coordinate pharmacovigilance activities [24]. Besides, there is also lack of awareness among health professionals about adverse drug reactions and pharmacovigilance [34, 35]. Although there are seven regional pharmacovigilance centres in Nepal, there is a lack of coordination between the centres and there is no process for disseminating reported adverse drug reactions to all the regional centres which has to be coordinated by the national pharmacovigilance centre. The national centre organizes a few seminars occasionally (once or twice in a two year time duration). Till date, there have been about 10 seminars organized since the initiation of pharmacovigilance activities in Nepal. Lack of information dissemination mechanisms is one of the potential lacunae for the existing pharmacovigilance program [36]. Underreporting of ADRs is another major limitation for efficient functioning of the pharmacovigilance program.

A recent systematic review analysing the causes of under-reporting mentions that only between 5 and 10% of ADRs are reported [37]. A systematic review published in 2006 had examined studies estimating under-reporting of ADRs [38]. The under-reporting rate by general practitioners ranged from 36% to more than 99% while for ADR reporting in the hospital setting under-reporting rates ranged from 59% to 100%. There are many factors reducing reporting rates by HCPs [39-41]. Their knowledge about and attitudes towards ADR and ADR reporting is an important factor [35]. Another important limitation is the system itself lacking the involvement of consumers as an official reporter for adverse drug reaction.

Initiating Consumers Pharmacovigilance in Lalitpur District
Role of healthcare professionals and community pharmacists in pharmacovigilance program of Nepal

Healthcare professionals are doctors, nurses, pharmacists, health assistants among others involved in health care service delivery. Healthcare professionals are in a better position to report ADR as they are in close contact with patients. There is a system of voluntary reporting of ADRs till now and all healthcare professionals can report ADRs. Studies has shown that HCPs can contribute significantly to the ADR monitoring process. There are many pharmacists who serve people and society as community pharmacists (CPs). They can be also considered as an important stakeholder in the pharmacovigilance framework. They have a very important role as a healthcare service provider. Community pharmacies are operated by persons having either diploma or bachelor’s degree in pharmacy in addition to the other professionals like nurses, health assistants, and other professionals like CMAs [42]. Patients generally prefer to visit community pharmacies for seeking advice for their health problems. Since, self-medication is common in Nepal CPs are a key stakeholder for directing the health care services towards using medicines safely. [43] It would be of great benefit to involve CPs in the national pharmacovigilance system to complement and reinforce the pharmacovigilance system. The reason behind this may be their contact with the patients on a daily basis for any drug related problems which would enable them to report ADRs.

1.9 CONSUMER REPORTING OF ADVERSE DRUG REACTIONS

Globally, the existing system for ADR reporting depends on mandatory and spontaneous reports submitted by doctors, pharmacists, and pharmaceutical companies thus limiting the experiences from consumers. Nepal does not have any system for involving consumers in the national pharmacovigilance program. There are many advantages for involving consumers as their rights can be reinforced for getting treated properly and reducing the possibility of any suspected adverse drug reactions [44].
When consumers become involved in the process, they can reinforce their rights and ensure that they receive proper care in the future. Consumers can provide more information about ADRs as they are the main consumers of medicine and suffer the negative consequences due to medicines. In addition, they can report some new types of reactions which has never been reported. Reports from consumers can increase the rate of ADR reporting and be an important indicator of the damage resulting from irrational use of medicines [45].

1.9.1 PROBLEM STATEMENT
Nepal a developing country in the South East Asia region, has established its own national pharmacovigilance program since 2004. However, the pharmacovigilance program is still in its infancy due to limited coverage of pharmacovigilance related activities. Pharmacovigilance can be regarded as the quality control system of the society for drug use surveillance. The aim is to reduce human suffering due to disease and drug related economic loss. The existing system for reporting ADRs is completely dependent on voluntary reporting by health care professionals as the main source of information [13]. Medical doctors along with other healthcare professionals should report ADRs as part of their professional responsibility. Healthcare professionals should be knowledgeable about the ADR reporting systems in their region and country and should be aware of the importance of reporting ADRs, but about 40% of healthcare professionals who could play an important role in reporting ADRs are not yet aware of the existence of the ADR reporting form developed by the national centre for healthcare professionals and its intended use as a reporting mechanism for suspected ADRs [44].

The national pharmacovigilance centre encourages ADR reporting by HCPs, but to date, as per DDA statistics, only 523 ADRs have been reported till the end of 2013. The WHO indicates that fully functional pharmacovigilance systems should expect to receive 200 ADR reports per year per million
population; for Nepal, that works out to be 6,097 ADR reports per year for its population of 30.5 million [34].

There are seven regional pharmacovigilance centres in Nepal till date. These centres are located at the Manipal Teaching Hospital (MTH), Pokhara, Tribhuvan University Teaching Hospital (TUTH), Kathmandu, Nepal Medical College Hospital (NMCH), Kathmandu, KIST Medical College, Lalitpur, Civil hospital, Kathmandu, Patan Academy of Health Sciences (PASH), Patan and BPKIHS Dharan. Out of the eight regional centres, five are located in the capital city Kathmandu and only two regional centres are located outside the Kathmandu valley. All these centres report ADRs to the national centre through a web based system for ADR reporting and management termed ‘Vigiflow’. There is no system of ADR reporting by consumers till date in Nepal. In certain developed countries, there is a separate form developed for consumers. They can even report ADRs through telephone and email to the concerned organizations.

Consumer pharmacovigilance is involvement of consumers in the ADR reporting process. This system was developed initially by Australia in 1964, followed by New Zealand and Canada and the United States of America in 1969. After these countries, Columbia, Hungary and Slovenia allowed patient reporting in the 1990s. After establishment of consumer reporting systems in these countries, several other countries initiated the service. The Netherlands started consumer ADR reporting in 2003, followed by Denmark in 2004. UK and Sweden started consumer pharmacovigilance in 2008 and in Norway in 2013 [47].

Thought the term “Consumer reporting” is used to refer for reporting of ADRs by the general public. Some of the countries use the term “patient reporting”, but consumer reporting is a broader term as all patients who consume medicines are consumers but not all consumers are patients. Hence, the broader term consumer was used instead of patients for involving patients in the ADR reporting process. Consumers can be an important stakeholder in the ADR reporting process. They can report problems caused by medicine use and reduce the chance of other people developing a similar reaction. Involvement of consumers in the ADR reporting program will encourage, support and
strengthen the existing system for pharmacovigilance in Nepal, where there are many challenges like self-medication, illiteracy and poverty.

Thus, due to the absence of involvement of consumers in the ADR reporting system, this study was conceptualized and initiated to explore the possibility of initiating consumer pharmacovigilance for supporting and strengthening the existing pharmacovigilance system.

KIST medical college was established in 2006 in Imadol VDC of Lalitpur district. This college is one of the regional pharmacovigilance centres and joined the pharmacovigilance program in 2008. About 250 ADR reports have been reported by the regional centre to the national pharmacovigilance centre.

1.9.2 RATIONALE FOR THE STUDY

Considering different problems with ADR reporting and the various limitations of the existing program, this study was conceptualized to explore the current status of knowledge, awareness and practice of pharmacovigilance and consumer pharmacovigilance among three groups of stakeholders, healthcare professionals, consumers and community pharmacists in Imadol area of Lalitpur district. Realizing the importance of integrating consumers in the existing pharmacovigilance program of Nepal, this study explored the possibilities and the possible advantages of consumer pharmacovigilance in Lalitpur district of Nepal.

There might be several advantages in terms of increased quality of life of patients, and promotion of consumer rights. It might also be easier for detecting the fake or counterfeit medicines as Nepal shares open borders with the neighbouring country of India. This might further increase and strengthen the efficiency of the Nepalese pharmacovigilance system. There is an urgent need for Nepal to involve consumers in ADR monitoring and drug safety issues due to the following reasons:

1. ADR reports from healthcare professionals are still much less than that expected considering the size of the country’s population. [34]
2. Under-reporting of ADRs is a major problem. [35]
3. Self-medication is very common in the Nepalese context. [43]
4. Extensive use of medicines without prescription. [34]
5. Use of herbal and traditional medicines. [45]
6. Promotion of consumer’s health rights. [48]

Patients and consumers have the right to participate, report and share their experiences and sufferings as a result of unwanted adverse effects which threaten their health and their lives. The participation of consumers in the process of drug safety monitoring would promote consumer health rights.

1.9.3 STUDY OBJECTIVES
This research was conducted with the following general and specific objectives:
1.9.3.a General Objective
The general objective of the research was to explore the knowledge, attitude and practice of pharmacovigilance and consumer pharmacovigilance among healthcare professionals, community pharmacists and consumers in Imadol VDC of Lalitpur district, Nepal and to plan educational interventions to address the noted deficiencies.

1.9.3.b Specific Objectives
1. To obtain information on knowledge and attitude about pharmacovigilance and consumer reporting of ADRs among health care professionals of KIST Medical College, consumers and community pharmacists in Imadol VDC, Lalitpur district, Nepal.

2. To obtain baseline demographic data with regard to age, gender, ethnicity, education level, occupation, working experience, etc. for healthcare professionals, community pharmacists and consumers.
3. To note the association of knowledge and attitude scores with demographic and other characteristics of health care professionals and community pharmacists both before and after an educational intervention.

4. To conduct an educational intervention and assess its effect on knowledge retention and formation of positive attitudes among the community pharmacists.

5. To study the knowledge about pharmacovigilance and consumer pharmacovigilance among consumers who visited KISTMCTH during the study period.

6. To design a suitable form for ADR reporting for consumers.

1.9.4 THESIS OVERVIEW

This thesis is divided into ten chapters.

1. **Chapter 1** is the introduction. The chapter deals with the general introduction to Pharmacovigilance, its requirement in various countries and also provides information about consumer pharmacovigilance.

2. **Chapter 2** deals with literature review about this topic. This chapter provides brief information related to pharmacovigilance and consumer pharmacovigilance along with its brief history and definition of terms used wherever necessary. It reviews various studies related to consumer pharmacovigilance and pharmacovigilance in developing and developed countries.

3. **Chapter 3** is about the methodology used in this research. The chapter describes methods used in the present research along with the calculation
of sample size for health care professionals, community pharmacists and consumers. It also contains the details of the questionnaires used. The chapter provides information on the methods used for pilot testing the questionnaires, face and content validation and reliability information for the questionnaires. It also describes the educational interventions carried out and retention of knowledge among healthcare professionals and community pharmacists. It also provides information about designing a suitable ADR reporting form for consumers.

4. **Chapter 4** describes the results of the present study. Statistically analyzed data along with their findings are tabulated for all three groups of the study population.

5. **Chapter 5** is the discussion and mentions the study limitations and summary.

6. **Chapter 6** describes the proposed interventions from the research findings.

7. **Chapter 7** concludes the research findings as thesis conclusion.

8. **Chapter 8** contains bibliography for the thesis.

9. **Chapter 9** has thesis publications related to the research work.

10. **Chapter 10** is Annex which contains the various questionnaires used for this study and various photographs for conducting this research.