

# **Chapter – 3**

## **Materials and Methods**

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### **3.0 Introduction**

The chapter describes the process in research methodology with the development of research design and the procedures followed for conduct of the study. It specifically illustrates instrument development, administering the instrument, sampling, data collection and analysis procedures, reliability and validity of the instrument. The processing of the data has been as per the Marketing Research Process (Burns & Bush, 2003).

### **3.1 Problem Statement**

To ascertain factors that have influence on doctors in prescribing generic medicines and understand the relationship between factors and prescription of generic drugs.

### **3.2 Rationale of the study**

Numerous studies have been carried out globally exploring perception, knowledge, attitude, practice etc. of generic medicines amongst population, patients, pharmacists and prescribers of generic medicines. (Bertoldi et al., 2005; Hassali et al., 2009; Toklu et al., 2012; Alrasheedy et al., 2014; Colgan et al., 2015; Kamejaliya et al., 2017; Aivalli et al., 2018).

Most of the studies conducted have been found to be in developed countries, further studies mostly in developing countries are required. Considering demographics and other factors, the need for cost savings and the decision making process for prescribing generic medicines is more in developing countries.

Most of the studies conducted to assess perception, knowledge, attitude etc. are focused on patients, customers and population however, limited studies are available focused on doctors (Hassali et al., 2009; Alrasheedy et al., 2014).

The studies available on perception of doctors towards generic medicines, largely limited to few tertiary care hospitals in India were mostly pilot in nature but were able to offer initial findings and valuable understandings to encourage further research in this under-researched area (Singh et al., 2016; Tripathi & Bhattacharya, 2018; Gupta et al., 2018).

With low patronage of generics by medical practitioners in India, the study aims to examine factors that influence doctors in prescribing generic medicines as doctors being the key decision making agents in the prescription decision.

Doctors are prescribers at a primary, secondary & tertiary healthcare centers. Availability of information concerning knowledge, attitude and practice of doctors in India towards generic drugs is limited. Hence, the aim of the study is to assess knowledge, attitude and practice of doctors at primary, secondary and tertiary care hospitals including government and private hospitals regarding practice of generic drugs to identify factors that encourages or obstructs recommendation of generic medicines.

A majority of Indian population (nearly 68%) has either inadequate or no access to essential medicines according to WHO report. Additionally, dispensation of free medicines in public healthcare services has dropped from 31.2% to 8.9% for inpatients and from 17.8% to 5.9 % for outpatients over the last two decades, according to a 2011

PHFI (Public Health foundation of India) study. OOPE expenses make up 62% of healthcare costs in India (USA, UK 20%, BRICS countries about 20-25%).

The study will be novel in the sense that apart from assessing level of understanding and attitude amongst the doctors of various specialties at primary, secondary and tertiary healthcare centers, it would explore, identify and address other contentious issues that doctors may have in prescribing generic medicines.

The study also intends to explore the marketing aspects of generic medicines that the pharmaceutical companies need to take into consideration on the basis of the outcome of the analysis of the study.

The study is of national importance that addresses the issue of low generic prescriptions despite high out-of-pocket expenses and majority of the population living in the rural area with low income.

To obtain a comprehensive measure of the doctors' responses, the research based on survey from doctor was undertaken.

### **3.3 Research Questions**

The research questions developed for the study are given in the Table 3.1

Table 3.1

## Research questions

Sr. No.	Research Question
<b>RQ 1</b>	<b><i>Does knowledge of generic medicines play a significant role in influencing doctors in prescribing generic medicines?</i></b>
RQ 1.1	<i>Is there any difference in knowledge of generic medicines amongst doctors serving at primary, secondary and tertiary healthcare centers?</i>
RQ 1.2	<i>Is there any difference in knowledge of generic medicines between Male and Female doctors?</i>
RQ 1.3	<i>Is there any difference in knowledge of generic medicines amongst doctors in different age groups?</i>
RQ 1.4	<i>Is there any difference in knowledge of generic medicines amongst doctors who are self-employed, working with Govt. hospitals, and Pvt. Hospitals?</i>
RQ 1.5	<i>Is there any difference in knowledge of generic medicines amongst doctors qualified with UG Degree, PG Diploma/Degree, and Post PG Degree?</i>
RQ 1.6	<i>Is there any difference in knowledge of generic medicines amongst doctors having practice involving non-surgical and surgical treatment?</i>
RQ 1.7	<i>Is there any difference in knowledge of generic medicines amongst doctors in different experience groups?</i>
<b>RQ 2</b>	<b><i>Does attitude towards generic medicines plays a significant role in influencing doctors in prescribing generic medicines?</i></b>
RQ 2.1	<i>Is there any difference in attitude towards generic medicines amongst doctors serving at primary, secondary and tertiary hospitals?</i>
RQ 2.2	<i>Is there any difference in attitude towards generic medicines between Male and Female doctors?</i>
RQ 2.3	<i>Is there any difference in attitude towards generic medicines amongst doctors in different age groups?</i>
RQ 2.4	<i>Is there any difference in attitude towards generic medicines amongst doctors who are self-employed, working with Govt. hospitals, and Pvt. Hospitals?</i>
RQ 2.5	<i>Is there any difference in attitude towards generic medicines amongst doctors qualified with UG Degree, PG Diploma/Degree, and Post PG Degree?</i>
RQ 2.6	<i>Is there any difference in attitude towards generic medicines amongst doctors having practice involving non-surgical and surgical treatment?</i>
RQ 2.7	<i>Is there any difference in attitude towards generic medicines amongst doctors in different experience groups?</i>
<b>RQ 3</b>	<b><i>Does practice of doctors play a significant role in influencing them in prescribing generic medicines?</i></b>
RQ 3.1	<i>Is there any difference in practice amongst doctors serving at primary, secondary and tertiary hospitals?</i>
RQ 3.2	<i>Is there any difference in practice between Male and Female doctors?</i>
RQ 3.3	<i>Is there any difference in practice amongst doctors in different age groups?</i>
RQ 3.4	<i>Is there any difference in practice amongst doctors who are self-employed, working with Govt. hospitals, and Pvt. Hospitals?</i>
RQ 3.5	<i>Is there any difference in practice amongst doctors qualified with UG Degree, PG Diploma/Degree, and Post PG Degree?</i>
RQ 3.6	<i>Is there any difference in practice amongst doctors giving non-surgical and surgical treatment?</i>
RQ 3.7	<i>Is there any difference in practice amongst doctors in different experience groups?</i>
<b>RQ 4</b>	<b><i>Is there any difference in practice of prescribing generic medicines amongst doctors serving at primary, secondary and tertiary healthcare centers?</i></b>
<b>RQ 5</b>	<b><i>Does Knowledge (cognitive) of generic medicine, Attitude (affective) towards generic medicine and Practice (conative) have a significant influence on doctors in prescribing generic medicines?</i></b>

### **3.4 Objectives of the study**

The objectives of this research are...

- I. To ascertain factors that have influence on doctors in prescribing generic medicines.
- II. To find out relationship between factors and prescription of generic medicines
- III. To compare level of influence associated with different factors on doctors at different healthcare delivery points – primary, secondary and tertiary healthcare care centers.
- IV. To evaluate if acceptance and use of generic medicine could be explained by Tri-component Model of Cognitive-Affective-Conative processes of decision making.
- V. To bring forth suggestions that may lead to increase in prescribing of generic medicines.
- VI. To suggest marketing aspects of generic medicines that the pharmaceutical companies need to take into consideration based on the outcome of the analysis of the study.

### **3.5 Formulation of Hypotheses**

Research hypotheses are educated predictive statements which are developed on the basis of research objectives as illustrated in section 3.4. It provides basis for analysis & evaluation of data and interpret findings. The hypotheses framed for the study are given in Table 3.2.

Table 3.2  
Hypotheses

Sr. No.	Hypothesis
<b>H 1</b>	<b>Knowledge of generic medicines plays a significant role in influencing doctors in prescribing generic medicines.</b>
H 1.1	There is no difference in knowledge of generic medicines amongst doctors serving at primary, secondary, and tertiary healthcare centers.
H 1.2	There is no difference in knowledge of generic medicines between Male and Female doctors.
H 1.3	There is no difference in knowledge of generic medicines amongst doctors in different age groups.
H 1.4	There is difference in knowledge of generic medicines amongst doctors who are self-employed, working with Govt. hospitals and Pvt. Hospitals.
H 1.5	There is no difference in knowledge of generic medicines amongst doctors qualified with UG Degree, PG Diploma/Degree, and Post PG Degree.
H 1.6	There is no difference in knowledge of generic medicines amongst doctors having practice involving non-surgical and surgical treatment.
H 1.7	There is no difference in knowledge of generic medicines amongst doctors in different experience groups.
<b>H 2</b>	<b>Attitude towards generic medicines plays a significant role in influencing doctors in prescribing generic medicines.</b>
H 2.1	There is no difference in attitude towards generic medicines amongst doctors serving at primary, secondary and tertiary hospitals.
H 2.2	There is difference in attitude towards generic medicines between Male and Female doctors.
H 2.3	There is no difference in attitude towards generic medicines amongst doctors in different age groups.
H 2.4	There is difference in attitude towards generic medicines amongst doctors who are self-employed, working with Govt. hospitals, and Pvt. Hospitals.
H 2.5	There is no difference in attitude towards generic medicines amongst doctors qualified with UG Degree, PG Diploma/Degree and Post PG Degree.
H 2.6	There is no difference in attitude towards generic medicines between doctors having practice involving non-surgical and surgical treatment.
H 2.7	There is no difference in attitude towards generic medicines amongst doctors in different experience groups.
<b>H 3</b>	<b>Practice of doctors plays a significant role in influencing them in prescribing generic medicines.</b>
H 3.1	There is no difference in practice amongst doctors serving at primary, secondary and tertiary hospitals.
H 3.2	There is no difference in practice between Male and Female doctors.
H 3.3	There is no difference in practice amongst doctors in different age groups.
H 3.4	There is difference in practice amongst doctors who are self-employed, working with Govt. hospitals and Pvt. Hospitals.
H 3.5	There is no difference in practice amongst doctors qualified with UG Degree, PG Diploma/Degree, and Post PG Degree.
H 3.6	There is no difference in practice amongst doctors giving non-surgical and surgical treatment.
H 3.7	There is no difference in practice amongst doctors in different experience groups.
<b>H 4</b>	<b>There is no difference in practice of prescribing generic medicines amongst doctors serving at primary, secondary and tertiary healthcare centers.</b>
<b>H 5</b>	<b>Knowledge (cognitive) of generic medicine, Attitude (affective) towards generic medicines and Practice (conative) have a significant influence on doctors in prescribing generic medicines.</b>

### **3.6 Scope of Study**

Dehradun district was selected for conduct of survey which is the capital city of Uttarakhand, a state in North India. The medical infrastructure is well developed with the presence of primary, secondary and tertiary healthcare centers. Both government and private sectors are engaged in providing healthcare treatment at Dehradun which has evolved as a major medical hub of the state.

The medical infrastructure includes four medical universities (1 government and 3 private), leading government & private hospitals, primary healthcare centers and independent practicing doctors.

### **3.7 Research Design**

The research design followed in the study is *descriptive*. Furthermore, the study uses cross-sectional analysis in order to describe statistical significance in associations between variables.

### **3.8 Sources of Data Collection**

Primary data was collected using questionnaire from the medical practitioners in the district of Dehradun.

Secondary data was collected from several sources including research papers, periodicals, printed literature about the industry, companies, books and websites.



### 3.9 Methods of Accessing Data

The questionnaire was self-administered amongst medical practitioners with face to face interaction. The medical practitioners were interviewed via phone, by email, and via Google-form due to the Covid 19 pandemic restrictions.

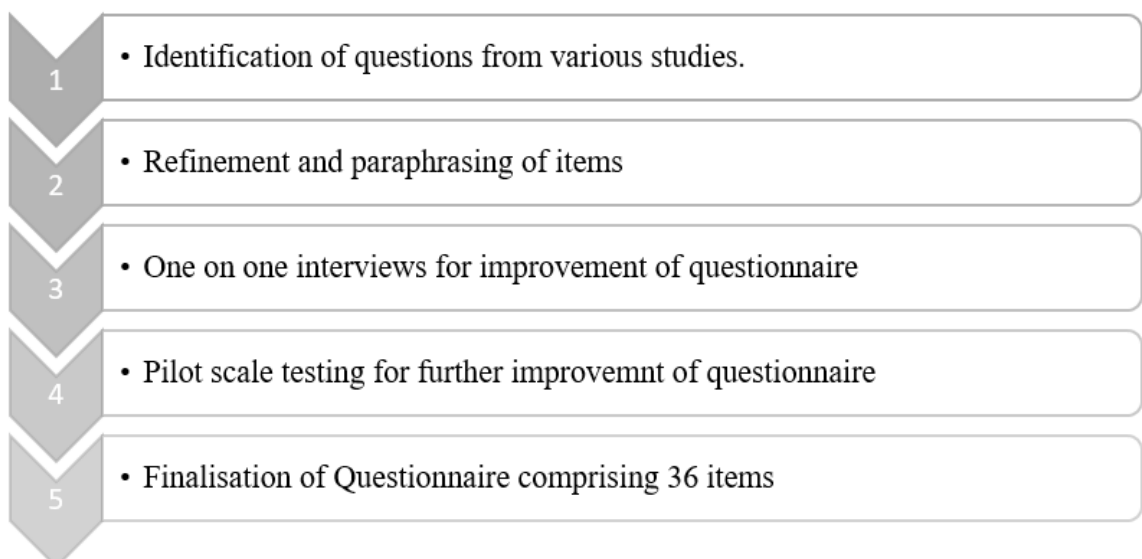
### 3.10 Data Collection Form

The questionnaire was designed as a data collection form which was used to ask and record information gathered during the research study.

### 3.11 Instrument Development

A structured questionnaire comprising thirty-six items connected with knowledge, attitude and practice of doctors towards generic drugs in Likert Scale was developed to collect the data.

The steps followed in the development process of the instrument are as follows:



### 3.11.1 Identification of questions from various studies

The development process started with literature review with a focus on identification of questions from various research studies that were conducted previously.

Based on the review of literature as illustrated above, the statements related to knowledge, attitude, practice and prescribing of generic medicines for the study have been identified which are given in the Tables 3.3, 3.4, 3.5, 3.6. Inclusion of additional statements related to generics at Jan Aushadhi were as per the recommendation of select doctors who were consulted during framing of questionnaire in different constructs.

Table 3.3  
Statements related to knowledge

Component	Previous Studies	Statements
Composition, dose and indications of generics same as branded / innovator medicine	(Gupta et al., 2015) (Gupta et al., 2018)	<i>Composition, dose and indications of generic medicines are same as branded / innovator medicine.</i>
Therapeutically equivalence of generics	(James et al., 2018)	<i>All generic products of a particular medicine that are rated as generic equivalents are therapeutically equivalent to each other.</i>
Interchangeability of innovator/branded drug with generics	(Gupta et al., 2015) (Badwaik et al., 2015) (Gupta et al., 2018)	<i>Generic drugs are usually intended to be interchangeable with an innovator / branded drug.</i>
Generics introduction after patent expiry of innovator	(Gupta et al., 2015) (Badwaik et al., 2015) (Gupta et al., 2018)	<i>Generic drugs can be only marketed after the expiry date of the patent of innovator.</i>
Jan Aushadhi awareness	(Badwaik et al., 2015) (Gupta et al., 2015) (Gupta et al., 2018)	<i>I have limited awareness about the Jan Aushadhi scheme of Government of India.</i>
IMA guidelines awareness for generic prescribing	(Badwaik et al., 2015) (Gupta et al., 2015) (Gupta et al., 2018)	<i>I am aware of Indian Medical Council guidelines to prescribe medicines by generic names in place of brand names.</i>
Bioequivalence of generic to brand	(Hassali et al. 2014) (James et al., 2018)	<i>A generic medicine is bioequivalent to a brand name medicine.</i>

Table 3.4  
Statements related to attitude

Component	Previous Studies	Statements
Comparative effectiveness of all generics with branded drugs	(Hassali et al., 2014)	<i>I believe all generic drugs are as effective as original drugs.</i>
Comparative effectiveness of generics at Jan Aushadhi with branded drugs		<i>I believe generic drugs available at Jan Aushadhi are as effective as original drugs.</i>
MNCs quality of medicines better than local companies	(James et al., 2018)	<i>I believe that medicines of multinational companies are of good quality than of local company.</i>
Limited reputable local generic drug companies	(Badwaik et al., 2015)	<i>I view few local companies as reputable generic drug companies.</i>
Branded medicines have higher safety standards	(Hassali et al., 2014) (James et al., 2018)	<i>Brand name medicines are required to meet higher safety standards than generic medicines.</i>
Influence on prescription by promotion of drug companies		<i>I believe promotion by the drug companies will influence my future prescribing pattern.</i>
Need of education about generic medicines	(Singh et al., 2016).	<i>I believe doctors should be educated more about generic medicines.</i>
Greater role by pharmacists as advisors on generic medicines	(James et al., 2018)	<i>I believe that pharmacists are one of the most important health care professionals to give advice on generic medicines.</i>
Hospital budget affects choice of medicine	(Hassali et al., 2014)	<i>Hospital budget for drug procurement factor will affect my choice of medicines.</i>
Need for confidence building for generic medicines amongst doctors	(Badwaik et al., 2015)	<i>I believe more confidence should be built among doctors about generic medicines.</i>
Variation in manufacturing standards between generics and brands	(Gupta et al., 2015)	<i>I believe brand-name drugs are usually made in modern manufacturing facilities, and generics are in substandard facilities.</i>

Table 3.5  
Statements related to practice

Component	Previous Studies	Statements
Price-Quality parity of generic drugs	(Badwaik et al., 2015) (Kamejaliya et., 2017)	<i>Generic drugs cost less but are as good as brand-name drugs.</i>
Price- Quality parity of generics at Jan Aushadhi		<i>Generic drugs of Jan Aushadhi cost less but are as good as brand-name drugs.</i>
Rewards to doctors for prescribing generics	(Badwaik et al., 2015)	<i>Incentives should be paid to doctors for prescribing generics.</i>
Substitution of branded drugs with generics	(Badwaik et al., 2015) (Gupta et al., 2018) (Kamejaliya et., 2017)	<i>Branded drug prescription should not be substituted by generic drugs.</i>
Liberty to choose generics by patient	(Badwaik et al., 2015)	<i>Patient should have the liberty to choose generics over branded drugs.</i>
Hesitation in prescribing in some diseases	(Badwaik et al., 2015)	<i>I hesitate to prescribe generics in few therapeutic cases / some diseases.</i>
Influence of personal experiences with medicines	(Badwaik et al., 2015)	<i>My prescription is influenced by my personal experience with medicines.</i>
Influence by patients' demands	(Badwaik et al., 2015) (Gupta et al., 2018)	<i>My prescription is influenced by the patients' demands.</i>
Consideration of socioeconomic status of patients for prescribing medicines	(Gupta et al., 2015) (Singh et al., 2016)	<i>I consider the socioeconomic status of the patient while prescribing medicines.</i>
Easy remembrance of brand names	(Badwaik et al., 2015) (Gupta et al., 2018)	<i>I prescribe branded drugs because their names are easy to memorize.</i>
Influence of medical reps	(Gupta et al., 2015) (Gupta et al., 2018) (Badwaik et al., 2015)	<i>Medical representatives influence my prescription</i>
Availability of medicines	(Gupta et al., 2015)	<i>I usually prescribe medicines that are easily available.</i>
Outcome of therapy with switching from brands to generics	(Gupta et al., 2015) (Badwaik et al., 2015) (Kamejaliya et., 2017) (Gupta et al., 2018)	<i>Switching a patient from a brand name to generics may change the outcome of the therapy.</i>
Comparison of safety & efficacy of generic vs. brand name medicines	(Gupta et al., 2015) (Singh et al., 2016) (Gupta et al., 2018)	<i>I have not read any time any article on comparison of safety and efficacy of generic vs. brand name medicines.</i>
Awareness seminars to prescribe generic drugs	(Gupta et al., 2015) (Gupta et al., 2018)	<i>Awareness seminars should be conducted for doctors to initiate prescription of generic drugs.</i>
Published Literature on generic drugs	(Singh et al., 2016)	<i>Published literature on generic drugs will develop doctor's confidence for its prescription.</i>
Mandatory prescribing of generics	(Kamejaliya et., 2017)	<i>Prescription of generic drugs should be made mandatory.</i>

Table 3.6  
Statement related to prescribing generic medicines

Component	Previous Studies	Statements
Prescribing generic drugs	(Gupta et al., 2015) (Badwaik et al., 2015) (Gupta et al., 2018)	<i>I usually prescribe generic drugs.</i>

### 3.11.2 Refinement and paraphrasing of items

As deemed appropriate for research purposes, the items were rephrased both in language and context.

Items from various studies were a mix of questions and statements which were restated as affirmative and negative statements.

Some of the Items duplicate in nature were merged in one.

Wordings of few statements were changed to avoid ambiguity in understanding meaning of the statements.

### 3.11.3 One on One interviews for improvement of questionnaire

The one on one interviews with select doctors and an interaction with a leading research company prior to pilot test brought out some of the shortcomings in the questionnaire which are listed below:

- The questionnaire is lengthy.
- Few of the items worded differently were still found to be duplicate in nature.
- Few new statements expanding the scope of study were missing.

### 3.12 Pilot Testing

The questionnaire was personally administered to 48 doctors.

Responses received to various items were tabulated in excel and checked for reliability test (Cronbach's Alpha) which was found to be above 0.80, details are given in the Table 3.7

Table 3.7  
Reliability Analysis (CRONBACH's ALPHA)

		N	%
Cases	Valid	46	95.8
	Excluded <sup>a</sup>	2	4.2
	Total	48	100.0

Reliability Statistics	
Cronbach's Alpha	N of Items
.828	36

For quick facilitation in selecting option from the choices, the list containing qualifications and specialty were enlarged with more options based on the analysis of the responses.

Pilot testing of the questionnaire involved the use of the respective scales in order to gain feedback on all parameters, such as knowledge, attitude, and practice of generic medicines.

#### 3.13.2 Finalization of Questionnaire

The finalized questionnaire duly tested is exhibited in Appendix A. All the statements are close ended except for demographic profiling. The details of questionnaire with variable definition and measurement is illustrated in Table 3.8

Table 3.8  
Variable definitions & measurements

Variable Name	Details of Measure
Knowledge	<p>Knowledge of respondents is determined with the measurement of responses on Likert scale covering the following:</p> <ul style="list-style-type: none"> <li>- Composition, dose and indications of generics same as branded / innovator medicine</li> <li>- Therapeutically equivalence of generics</li> <li>- Interchangeability of innovator/branded drug with generics</li> <li>- Generics introduction after patent expiry of innovator</li> <li>- Jan Aushadhi awareness</li> <li>- IMA guidelines awareness for generic prescribing</li> <li>- Bioequivalence of generic to brand</li> </ul> <p>7 statements are asked on a scale of 1 to 5 (where 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, and 5=Strongly Agree)</p>
Attitude	<p>Attitude of respondents is determined by measuring responses on Likert scale covering the following:</p> <ul style="list-style-type: none"> <li>- Comparative effectiveness of all generics with branded drugs</li> <li>- Comparative effectiveness of generics at Jan Aushadhi with branded drugs</li> <li>- MNCs quality of medicines better than local companies</li> <li>- Limited reputable local generic drug companies</li> <li>- Branded medicines have higher safety standards</li> <li>- Influence on prescription by promotion of drug companies</li> <li>- Need of education about generic medicines</li> <li>- Greater role by pharmacists as advisors on generic medicines</li> <li>- Hospital budget affects choice of medicine</li> <li>- Need for confidence building for generic medicines amongst doctors</li> <li>- Variation in manufacturing standards between generics and brands</li> </ul> <p>11 statements are asked on a scale of 1 to 5 (where 1=Strongly Disagree 2=Disagree, 3=Neutral, 4=Agree, and 5=Strongly Agree)</p>
Practice	<p>Practice of respondents is measured based on responses to items covering the following areas;</p> <ul style="list-style-type: none"> <li>- Price-Quality parity of generic drugs</li> <li>- Price- Quality parity of generics at Jan Aushadhi</li> <li>- Rewards to doctors for prescribing generics</li> <li>- Substitution of branded drugs with generics</li> <li>- Liberty to choose generics by patient</li> </ul>

	<ul style="list-style-type: none"> <li>- Hesitation in prescribing in some diseases</li> <li>- Influence of personal experiences with medicines</li> <li>- Influence by patients' demands</li> <li>- Consideration of socioeconomic status of patients for prescribing medicines</li> <li>- Easy remembrance of brand names</li> <li>- Influence of medical reps</li> <li>- Availability of medicines</li> <li>- Outcome of therapy with switching from brands to generics</li> <li>- Comparison of safety &amp; efficacy of generic vs. brand name medicines</li> <li>- Awareness seminars to prescribe generic drugs</li> <li>- Published Literature on generic drugs</li> <li>- Mandatory prescribing of generics</li> </ul> <p>17 statements are asked on a scale of 1 to 5 (where 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, and 5=Strongly Agree)</p>
Prescription	Response to statement on <i>prescribing generic drugs</i> is measured on a scale 1 to 5 (where 1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, and 5=Strongly Agree)
Demographic Variables	<p>The respondents were asked:</p> <ul style="list-style-type: none"> <li>- Gender (1=Male, 2=Female)</li> <li>- Age (1=less than 30 years, 2=31-40 years, 3=41-50 years, 4=51-60 years, 5=more than 60 years)</li> <li>- Healthcare Center (1=Primary, 2=Secondary, 3=Tertiary)</li> <li>- Employment (1=Self-employed, 2=Govt. Hospital, 3=Private Hospital)</li> <li>- Numbers of years of practice</li> <li>- Highest Qualification (1=UG Degree, 2= PG Diploma/Degree, 3= Post PG Degree)</li> <li>- Specialty (1=Non-Surgical, 2=Surgical)</li> </ul>



### **3.14 Sampling Plan**

The sampling plan is detailed as follows:

#### **3.14.1 Population**

The study is based on the responses of doctors in the talukas of Dehradun district who are members of Indian Medical Association of Uttarakhand.

#### **3.14.2 Sampling Frame**

The sampling frame for the study was done after due diligence. The list of doctors was sorted based on first name of doctors. The population list comprised 671 doctors and the sample size is 200 doctors which is almost one-third the population size. For selection of sample from the population list three sampling lists were drawn which were then followed in contacting doctors for collection of data using systematic random sampling technique.

#### **3.14.3 Sample Unit**

Doctor is the sampling unit for the study.

#### **3.14.4 Sample Size**

Sample size, representative of population has been determined as follows:

At 95% confidence level, applying the highest level of variability and considering 5% sample error, 179 respondents are estimated (Burns & Bush, 2003)

Calculations for sample size (n) is determined as follows:

$$n = (Z_{\alpha/2})^2 pq / d^2 = [(1.96)^2 * (50^2)] / 5^2 = 384$$

$$d = Z_{\alpha/2} \sqrt{[(1/n + 1/N) pq]} = 1.96 \sqrt{[(\frac{1}{384} + \frac{1}{671}) * (50 * 50)]} = 6.2671$$

Where

N = population size,

p = 50% unknown,

q = 50% (100 – p), d = 5%,

$\alpha$  = 5% level of significance.

Minimum sample size

$$= (Z_{\alpha/2})^2 pq / [d^2 + (Z_{\alpha/2}^2 pq / N)] = 1.96^2 * 50^2 / [6.2671^2 + (1.96^2 * 50^2 / 671)] = 179$$

The sample size was set at 200, 671 doctors were contacted personally of which 228 responded.

### 3.15 Sampling Procedure

Systematic Random sampling was followed.

The list of members of IMA, Uttarakhand giving details of doctors was segregated to identify doctors at Dehradun district. The list of identified doctors was divided into three groups A, B, C using systematic random sampling technique. The doctors were then contacted starting with list A, followed by B & C.

### 3.16 Contact method

During the pilot and actual survey stage, the questionnaires were administered personally and responses filled in the form by interviewing the sample units and getting responses by google form.

The sample size comprised a total of 228 usable responses to questionnaire, representing 100 percent success rate.

A sample size of 48 respondents was used for the pre-test of the questionnaire. The survey was completed over a period of eleven months. There were a variety of respondents in the study on the basis of gender, different age groups, healthcare centers, employment, number of years of medical practice education, qualification, surgical, non-surgical practice to minimize any bias.

### **3.17 Collection of Data**

The questionnaire was personally administered to collect the data to minimize the non-sampling error. The data collected was tabulated in excel sheet details of which are given in Appendix B.

### **3.18 Analyzing Data**

In data analysis, data was entered into computer files, checked for errors, tabulated, and various statistical tests were conducted after data cleaning.

### **3.19 Reliability and Validity of the Instrument**

In the research study, the multi-item scales measuring consistency in responses from doctors were tested for reliability by determining Cronbach's alpha. The Table 3.9 exhibits Alpha value for each of the 36 variables above the minimum acceptable level of 0.60. The thirty-six variables comprise of seven items for knowledge, eleven for attitude, seventeen for practice and one for prescription of generics. To be specific, the overall Cronbach's alpha value is in excess of 0.80.

Table 3.9  
Reliability Analysis (CRONBACH's ALPHA)

Case Processing Summary			
		N	%
Cases	Valid	217	95.2
	Excluded <sup>a</sup>	11	4.8
	Total	228	100.0

Cronbach's Alpha	Cronbach's Alpha Based on Standardized Items	N of Items
.815	.814	36

Summary Item Statistics

	Mean	Minimum	Maximum	Range	Maximum / Minimum	Variance	N of Items
Item Means	3.245	2.101	4.101	2.000	1.952	.337	36
Item Variances	.903	.356	1.458	1.102	4.096	.093	36

	Mean	Minimum	Maximum	Range	Maximum / Minimum	Variance
Inter-Item Correlations	.108	-.292	.765	1.057	-2.617	.029

## Item Statistics

	Mean	Std. Deviation	N
<i>Composition, dose and indications of generics same as branded / innovator medicine</i>	3.82	.873	217
<i>Therapeutically equivalence of generics</i>	3.09	1.054	217
<i>Interchangeability of innovator/branded drug with generics</i>	3.51	.958	217
<i>Generics introduction after patent expiry of innovator</i>	2.86	1.041	217
<i>Jan Aushadhi Awareness</i>	2.88	1.200	217
<i>IMA Guidelines Awareness for generic prescribing</i>	4.04	.615	217
<i>Bioequivalence of generic to brand</i>	3.16	1.030	217
<i>Comparative effectiveness of all generics with branded drugs</i>	2.91	1.085	217
<i>Comparative effectiveness of generics at Jan Aushadhi with branded drugs</i>	3.09	.891	217
<i>MNCs quality of medicines better than local companies</i>	2.63	1.034	217
<i>Limited repuTable local generic drug companies</i>	2.23	.652	217
<i>Branded medicines have higher safety standards</i>	2.75	1.091	217
<i>Influence on prescription by promotion of drug companies</i>	3.06	1.145	217
<i>Need of education about generic medicines</i>	3.95	.826	217
<i>Greater role by pharmacists as advisors on generic medicines</i>	3.12	1.207	217
<i>Hospital budget affects choice of medicine</i>	3.49	.996	217
<i>Need for confidence building for generic medicines amongst doctors</i>	4.07	.604	217
<i>Variation in manufacturing standards between generics and brands</i>	3.13	.919	217
<i>Price-Quality parity of generic drugs</i>	3.19	1.008	217
<i>Price- Quality parity of generics at Jan Aushadhi</i>	3.18	.861	217
<i>Rewards to doctors for prescribing generics</i>	3.82	.991	217
<i>Substitution of branded drugs with generics</i>	2.68	1.069	217
<i>Liberty to choose generics by patient</i>	3.76	.999	217
<i>Prescribing generic drugs</i>	3.14	1.000	217
<i>Hesitation in prescribing in some diseases</i>	2.39	.947	217
<i>Influence of personal experiences with medicines</i>	4.10	.627	217
<i>Influence by patients' demands)</i>	3.23	1.118	217
<i>Consideration of socioeconomic status of patients for prescribing medicines</i>	2.10	1.009	217
<i>Easy remembrance of brand names</i>	3.76	.896	217
<i>Influence of medical reps</i>	3.70	1.032	217
<i>Availability of medicines</i>	4.02	.597	217
<i>Outcome of therapy with switching from brands to generics</i>	2.97	1.011	217
<i>Comparison of safety &amp; efficacy of generic vs. brand name medicines</i>	2.43	.900	217
<i>Awareness seminars to prescribe generic drugs</i>	3.99	.677	217
<i>Published Literature on generic drugs</i>	4.10	.666	217
<i>Mandatory prescribing of generics</i>	2.51	1.028	217

It was determined from the test that the instrument was reliable and valid. Therefore, no changes had to be made to the instrument.

### 3.20 Demographic Profile of the sample

Table 3.10 represents demographic characteristics of the overall sample comprising 228 respondents in total.

Table 3.10  
Demographic characteristics of overall sample

Gender	Male	168	73.7
	Female	60	26.3
	Total	228	100.0
Age Group	<30	4	1.8
	31-40	47	20.6
	41-50	59	25.9
	51-60	39	17.1
	>60	79	34.6
	Total	228	100.0
Healthcare Center Type	Primary Care	56	24.6
	Secondary Care	85	37.3
	Tertiary Care	87	38.2
	Total	228	100.0
Employment	Self-employed	106	46.5
	Govt. Hospital	44	19.3
	Pvt. Hospital	78	34.2
	Total	228	100.0
Qualification Categorization	UG Degree	27	11.8
	PG Diploma / Degree	184	80.7
	Post PG Degree	17	7.5
	Total	228	100.0
Specialty Categorization	Non-Surgical	128	56.1
	Surgical	100	43.9
	Total	228	100.0
Experience Group	Up to 5	20	8.8
	6-10	25	10.9
	11-20	61	26.7
	21-30	46	20.2
	>30	74	32.5
	missing	2	0.9
	Total	228	100.0

3.16.2 The demographic responses are shown in figures from 3.1 to 3.7

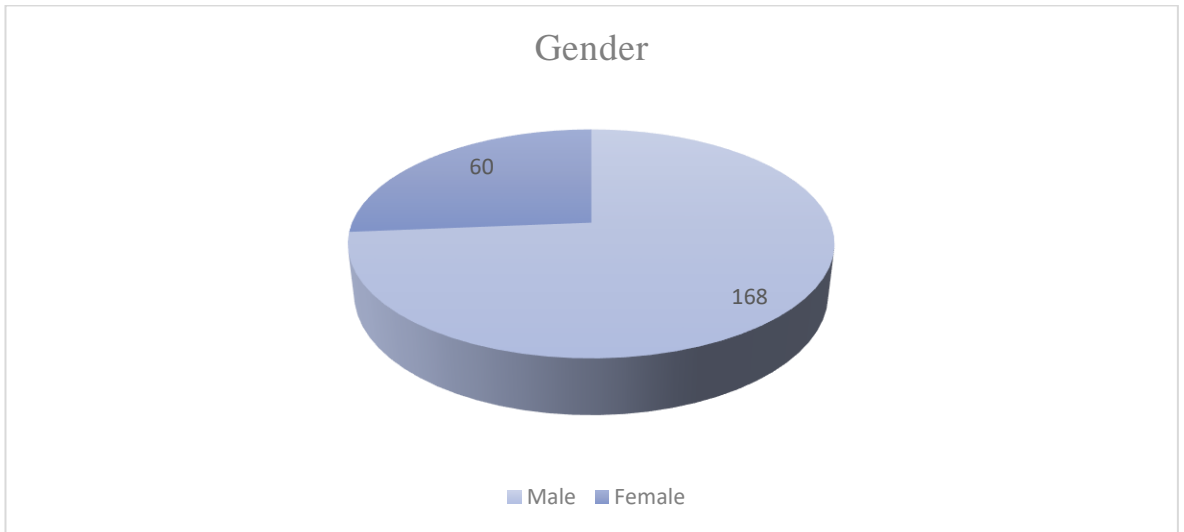


Figure 3.1 Gender of Respondents

Males dominate the sample constituting 74% of responses. Of the 228 respondents participating in the survey 168 were males and 60 were females.

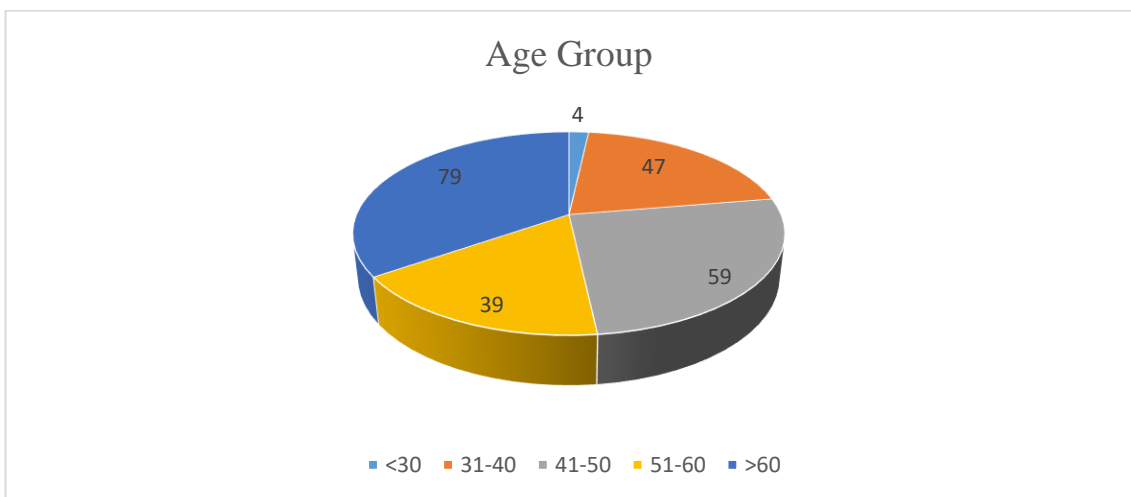


Figure 3.2 Age of Respondents

The sample has dominance of respondents having age more than 60 years at 35% followed by age group 41-50 years at 26%, 31-40 years at 20%, 51-60 years at 17% and less than 30 years at 2%.

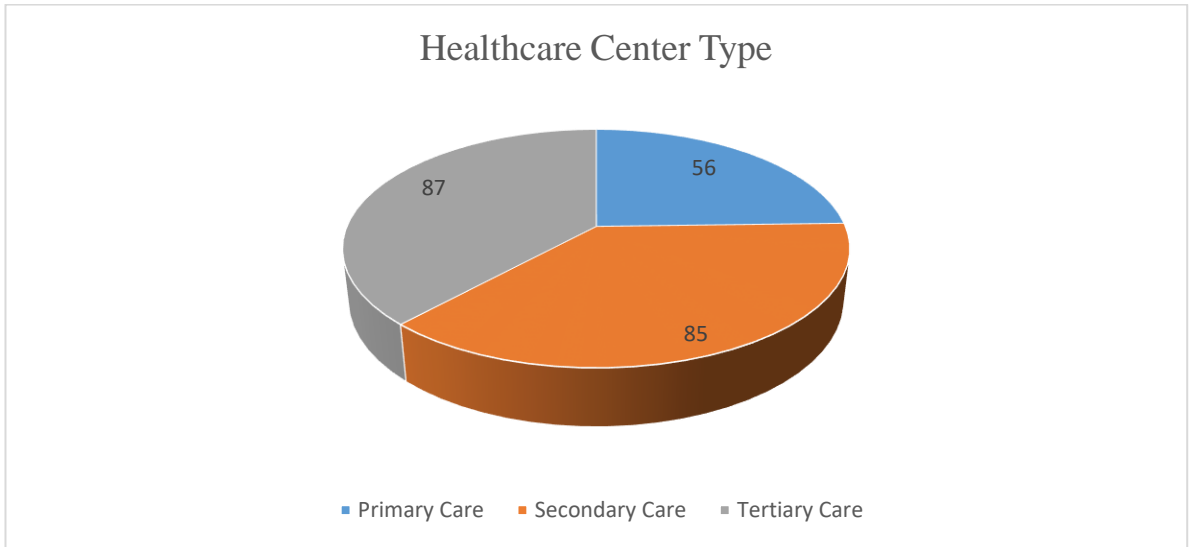


Figure 3.3 Healthcare Center Type

Respondents from Tertiary-care center were at 38% followed by Secondary-care at 37% and Primary-care at 25%

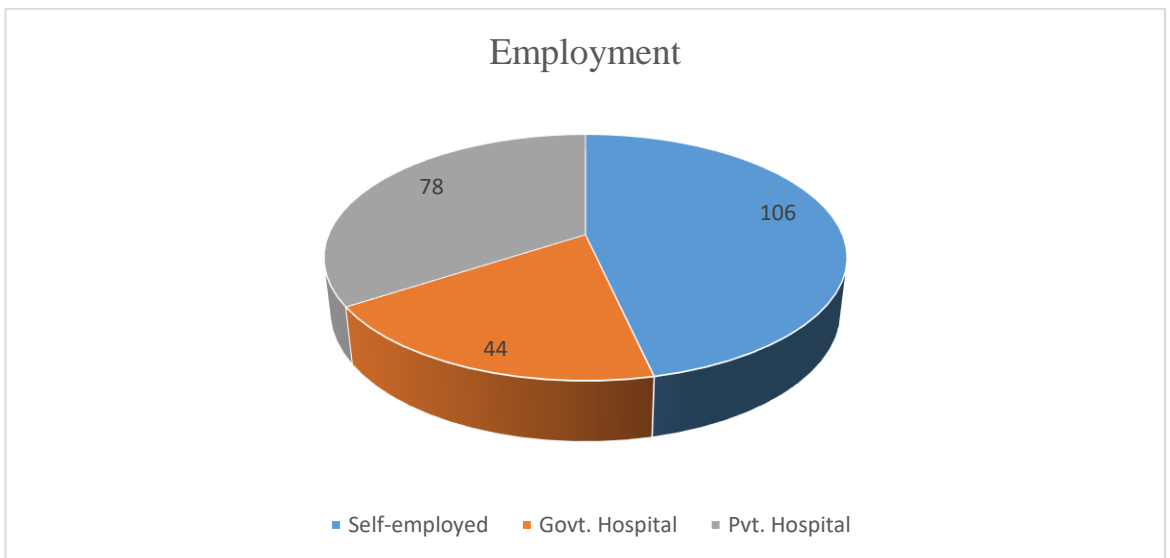


Figure 3.4 Employment of Respondents

Majority of the respondents constituting 47% were self-employed followed by 34% employed in Private Hospitals, and 19% with Government Hospitals.



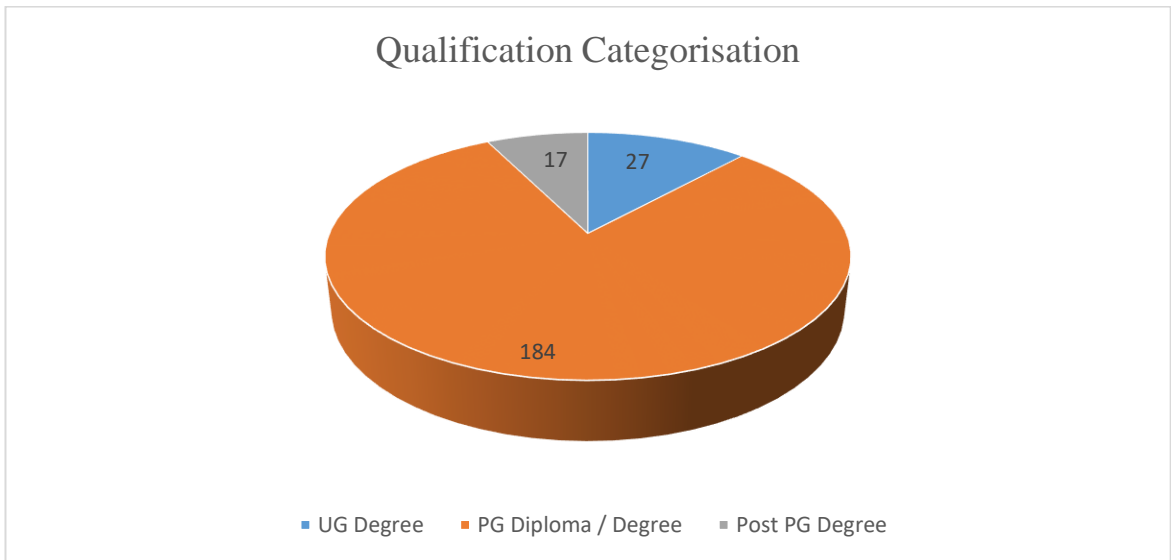


Figure 3.5 Qualification Categorization of Respondents

184 respondents constituting about 81% were qualified with PG Degree/Diploma. 27 (12%) of the respondents were qualified with UG Degree and the rest 17 respondents (7%) with Post PG qualification.

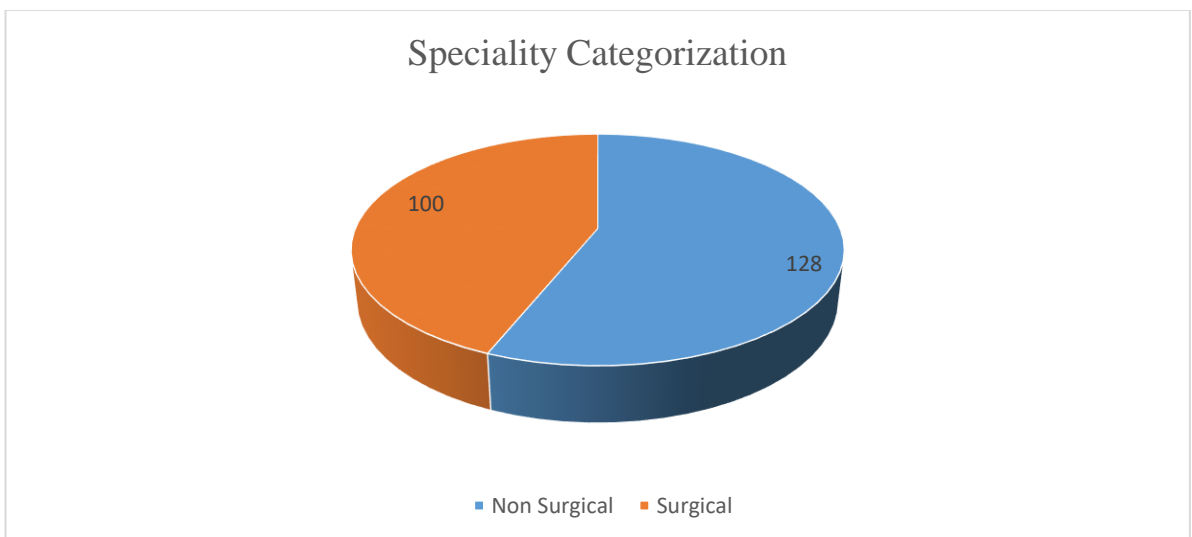


Figure 3.6 Specialty Categorization of Respondents

Majority of the responses at 56% were from doctors having specialization with non-surgical practice while the remaining 44% were having specialization which involved surgical treatment.

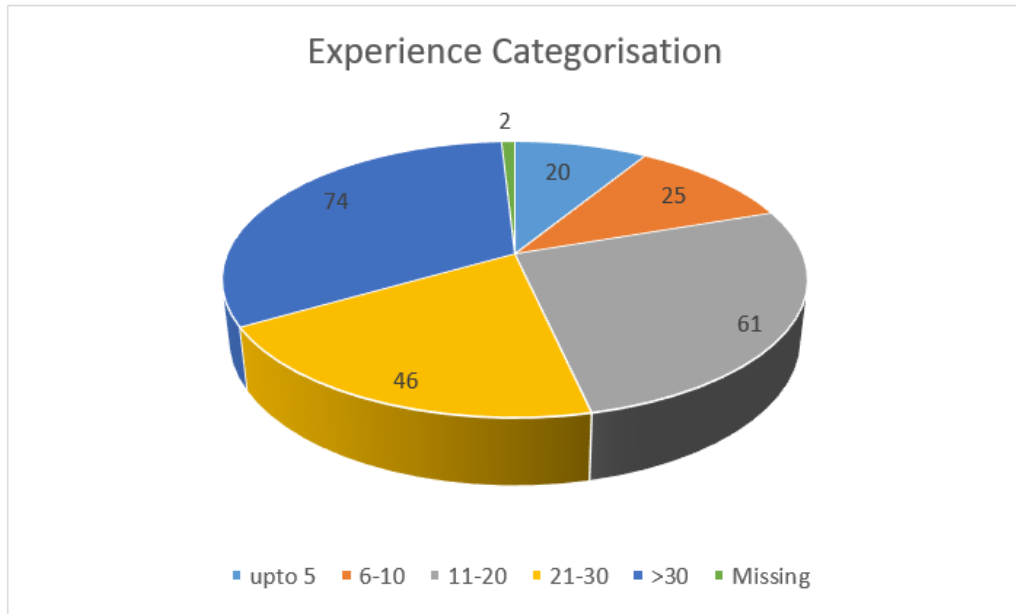


Figure 3.7 Experience categorization of respondents

Doctors with experience more than 30 years constitute 32% followed by 11-20 years (27%), 21-30 years (20%), 6-10 years (11%) and up to 5 years (9%)

The detailed analysis follows through the next chapter.