Chapter 6

METHODOLOGY

6.1 Study Settings

6.1.1 Design

A cross sectional, general population survey was conducted from 2013 to 2015 among urban young adults of East Sikkim in the age group of 15-40 years.

6.1.2 Sites

Proposed study site included an urban area in East Sikkim. The selected urban site was Gangtok, East Sikkim, the most important city in Sikkim. Identification of Gangtok as urban site was based on criteria provided by Urban Development and Housing Department (UDHD), Government of Sikkim, Gangtok.

6.2 Selection of Subjects

Youth is defined as men and women in the age group of 15 - 24 years (Parasuraman, 2009) and young adults are considered up to the age of 40 years (Erikson, 1965).

Inclusion Criteria: In this study only young adults (15 - 40) years of age of either sex were enrolled as participants, i.e, any subject satisfying the age criteria for inclusion was eligible. Individuals consuming analgesics with or without prescription and also those not consuming analgesics were included in the study. We have considered participants of Indian origin from the different ethnic backgrounds which includes the major ethnic communities of Sikkim; i.e, the Nepalis, Lepchas, Bhutias and also participants from Other ethnic groups like Bengalis, Biharis, Marwaris; etc from different states of the Indian population.
Exclusion Criteria: Any subject not satisfying the age criteria were excluded from the study. Young adults were chosen because as this population were less likely to have co-morbid age-related chronic medical conditions requiring regular analgesic use, more likely to develop adverse consequences of regular analgesic use like gastrointestinal and renal adverse events as well as dependence over their lifetime and this population was the best group for prevention measures.

6.3 Sampling Method and Size

Gangtok is a municipality, the capital and the largest town of the Indian state of Sikkim. It is located in the eastern Himalayan range, at an elevation of 1,650 m (5,410 ft). The town’s population belongs to different ethnicities such as Nepalis, Lepchas and Bhutias. Approximately 53% of the population of Gangtok are males and 47% females. Ethnic Nepalis, who settled in the region during British rule, comprise the majority of Gangtok’s residents, Lepchas native to the land and Bhutias also constitute a sizeable proportion of the population. Additionally a large number of Tibetans have immigrated to the town. Other immigrants not native to the region include the Marwaris, the Biharis and the Bengalis. Hinduism and Buddhism are the most significant religions in Gangtok. Nepali is the most widely spoken language in Sikkim as well as in Gangtok (Gangtok India Page, Global Gazettee, Version 2.1). The population of Gangtok when the study was designed was 98,658 (Office of the Registrar General and Census Commissioner, 2011), i.e., approximately 1,00,000.

According to current population pyramid of India approximately 35% of the total population belongs to the age group of 15 - 40 years (Technical Group on Population Projections - Registrar General of India (RGI), 1996). Therefore, in Gangtok, an approximate 35,000 people were expected to be in the age group of 15 - 40.
Prevalence of regular analgesic use in age groups above 14 years has been reported in the range of 7.2 to 34.8% in European studies. Thus, sample size was calculated using the formulae; (Sample size calculation - Cross-sectional studies, 2014)

\[ n = \frac{z^2pq}{d^2} \]

where \( n \) = required sample size

\( z = \) probability factor=1.96

\( p = \) proportion of the population having the characteristic,

(https://shodganga.inflibnet.ac.in, Determination of appropriate Sample Size)

\( q = 1 - p \)

\( d = \) degree of precision (acceptable margin of error)

To detect this prevalence at a 95% confidence interval, a lower limit of margin of error of 2% was considered.

Minimum sample size, \( n = \frac{z^2pq}{d^2} \)

\[ = \frac{(1.96)^2 \cdot 0.07 \cdot 0.93}{0.0004} \]

\[ = 625.2204 \]

\[ = 625 \text{ (Approx)} \]

Further stratification according to age group and gender was carried out.

Thus, to detect the prevalence at a 95% confidence interval (CI), the study enrolled \( n=700 \) participants from the urban Gangtok site.

The sampling strategy involved identification of sampling locations in each site.

Sampling locations were schools (age group of 15 - 17 years), colleges (age group of 18 - 22 years) and households where people in the age group of 15 - 40 years commonly aggregate and live. The study did not involve only a household survey, but
assumed a more ethnographic approach.

Let’s take an example of the first ward chosen, i.e, Ranipool. We started from one particular zone or one particular direction of Ranipool and identified the houses and numbered them as House Number 1, 2, 3……., so on. Next step was to chose the first house by simple random lottery method (say the first house visited was House Number 2, and if the house had satisfied the criteria of eligible study population we had collected the data. If a house had more than one eligible study population, we had considered all of them, provided the subjects had consented for participation in the study. When a house was locked, we had visited the house at least thrice, then again chosen our next house though the lottery method. When a house didn’t give consent for participation in the study, we moved on to the next house through the same lottery method. Thus data collection was done based on the lottery method from the houses representing the eligible study population (Shannon HS, et al. (2012).

According to the Census 2011, Gangtok city was divided into 15 (fifteen) wards. We had chosen 6 (six) wards (total population in 6 wards = 36,318) by simple random method with population in numbers as follows - Ranipool (4520), Tadong (9325), Daragaon (9605), Deorali (6938), Tibet Road (3266), Upper MG Marg (2664).

The sample size of our study is n=700. Let’s consider our first ward, Ranipool which has a population of 4,520; that represents

\[ \frac{4,520}{\text{Total population of 6 wards chosen}} \times 100 \]

\[ = \frac{4,520}{36,318} \times 100 \]

\[ = 12.45\% \]

Eligible study population in each ward was calculated as, Ranipool (4,520), i.e, 12.45% of 700

\[ = \frac{12.45}{100} \times 700 \]

\[ = 87.15 \text{ (87 samples approximately)} \]
Thus, the population percentage in each ward and the eligible study population in each of the 6 (six) wards were found out (Probability proportionate to size). Numbers of samples from each ward as calculated was

i. 87 samples from Ranipool

ii. 180 samples from Tadong

iii. 134 samples from Deorali

iv. 185 samples from Daragaon

v. 63 samples from Tibet Road

vi. 51 samples from Upper M.G Marg

Among the 87 (eighty seven) samples collected from Ranipool, 40 (forty) were from schools and 47 (forty seven) from 12 (twelve) houses. From Tadong, 75 (seventy five) included schools, 38 (thirty eight) from colleges and 67 (sixty seven) samples from 17 houses. 134 (one thirty four) samples were collected from 33 (thirty three) houses in Deorali. Out of 185 (one eighty five) samples from Daragaon, 40 (forty) were from schools and 145 (one forty five) from 49 (forty nine) houses. 63 (sixty three) samples were collected from 18 (eighteen) houses in Tibet Road. The last ward we had chosen was Upper M.G Marg which included 51 (fifty one) samples from 11 (eleven) houses.

The schools and colleges identified for data collection were Ranipool School, Ranipol, Gangtok, Tadong School, Tadong, Gangtok, Sikkim University, Tadong, Gangtok and Bahai School, Daragaon, Gangtok.

6.4 Instruments

The source document was a validated case record form constituting the following.

i. A generic sociodemographics section (e.g., age, gender, education, ethnicity etc.), which is a 21-item questionnaire including questions on alcohol use and smoking.
ii. A generic analgesic misuse questionnaire, comprising measures of non-steroidal and opioid analgesic use without medical advice, which is a 21-item questionnaire including information on treatment of pain and ease of availability of analgesics.

iii. Brief Pain Inventory - Short Form, which is a standardized instrument for assessment of pain. Brief Pain Inventory (BPI) is a 9-item instrument assessing pain in different domains of functionality from a participant’s perspective. It has been reported that BPI satisfies most of the key recommendations outlined in the draft guidance for assessing a pain-reduction treatment effect. The draft guideline was recommended in 2006 by United States Food and Drug Administration (FDA) on the use of patient-reported outcomes (PRO) measures in Medical Product Development to support labeling claims. This draft guidance outlines psychometric aspects that should be considered when designing a PRO measure, including conceptual framework, content validity, construct validity, reliability and the ability to detect clinically meaningful score changes (Atkinson et al., 2009).

iv. SF - 36, quality of life questionnaire, which is an 11-item standardized instrument for assessment of quality of life in different domains. Considerable evidence was found for the reliability of the SF-36 (Cronbach's alpha greater than 0.85, reliability coefficient greater than 0.75 for all dimensions except social functioning) and for construct validity in terms of distinguishing between groups with expected health differences. The SF-36 was able to detect low levels of ill health. The SF-36 was reported as a promising new instrument for measuring health perception in a general population. It is easy to use, acceptable to patients and fulfils stringent criteria of reliability and validity (Brazier et al., 1992).
Because pain is subjective, the patient’s self report provides the most valid measure of the experience. In our study we have graded pain using the Verbal Rating Scale (VRS). The VRS consists of a line of adjectives describing different levels of pain intensity. VRS of pain intensity should include adjectives that reflect the extremes of this dimension from “no pain” to “extremely intense pain” and sufficient additional adjectives to capture gradations of pain intensity that may be experienced between these two extremes. The one we have used in our study is the most commonly used 4 point scale of no pain = 0, mild = 1, moderate = 2, severe = 3. VRSs are usually scored by listing the adjectives in order of pain severity and assigning each one a score as a function of its rank.

6.5 Ethical Issues
This study consisted of only interviews and subsequent data analysis from questionnaires and did not involve any intervention. The study protocol, instruments and informed consent were approved by Institutional Ethics Committee (IEC) and Research Protocol Evaluation Committee (RPEC) of Sikkim Manipal Institute of Medical Sciences, Gangtok.
Informed consent was explained & obtained from each participant before enrolment in this study. They were provided with a copy of informed consent form with contact information of investigators so that they can contact the investigator or ask questions regarding the study. Responses of the questionnaires were coded by numbers and at no time participant’s name / photo were associated with participant’s responses to the questionnaire so that full confidentiality was maintained. Participation for this study was voluntary. At any time participant had complete freedom to withdraw from the study, if desired so. Participants were assured that this study did not have any relation with police or with their employment.
6.6 Statistical Analysis and Interpretation of Data

Statistical Package for Social Sciences (SPSS), version 20 was adopted for development of the databases as well as for carrying out statistical analysis. Before analysis all entries were checked and cleaned by ignoring or putting missing value codes for inconsistent or ambiguous values.

Descriptive statistics of variables of interest were considered. The mean and standard deviation (SD) were presented for continuous variables. The number and percent of study participants practicing a particular behaviour were reported for categorical variables. As variables were mostly nominal and ordinal, chi-square test of statistical significance was carried out. Frequency distribution was used to describe nature, extent and patterns of analgesic use. Effects of socio-demographic covariates, e.g., age, gender, occupation, education etc., on measures of analgesic use were analyzed using Chi-Square test for non-parametric data. Covariates predicting analgesic use were described by linear or logistic regression analysis depending on the characteristic of the analgesic use variable. Acceptable level of significance was set at \( p \leq 0.05 \).