CHAPTER 3

MATERIALS AND METHODS
The present community based study entitled “A Comparative study to assess Oro- Dental Variations and Oral Health Status in children born out of Consanguineous and Non Consanguineous marriages” was conducted in Aligarh city (Municipal Corporation); Uttar Pradesh, India.

PROFILE OF ALIGARH CITY

3.1: GEOGRAPHICAL SITUATION:
Aligarh city is situated in Western Uttar Pradesh, about 133 kilometres southeast of Delhi on Delhi – Calcutta railway line and Grand Trunk Road route in Western Uttar Pradesh. The latitude is 27 degree 54 min North and longitude is 78 degree 5 min East. Aligarh city comprises of an area of 226.9 square kilometres. An internationally accredited University i.e. Aligarh Muslim University (A.M.U) is situated in the city. Aligarh city is fortunate enough in having the best Medical and Health facilities; provided by 1050 bedded hospital of Jawaharlal Nehru Medical College, Dr.Z.A.Dental College, Tibbiya College, Institute of Ophthalmology, Rajiv Gandhi institute of Diabetes and Endocrinology, Cardiology centre and the recently built Trauma centre under AMU. On the other hand, State Government’s Medical and Health Services also cater to the needs of the public through the network of civil, referral and ESI hospitals.

3.2: CLIMATIC CONDITION:
Climate in Aligarh city is dry with maximum temperature reaching up to 47 degree centigrade in summers. The minimum temperature is 6 degree centigrade in winter season. Average rainfall is about 22 inches. The rain normally starts in the second half of July and lasts up to first half of September.

3.3: POPULATION PROFILE:
The population of Aligarh city is 8,74,408 persons spread over 70 wards living in 147363 number of households. The sex ratio is 882 females per 1000 males. The
population density of the city is 536.4 persons per square kilometre and the average literacy rate is 67.85% \[102\]

3.4: TYPE AND DESIGN OF STUDY:
Household survey using a cross-sectional study design was planned. Cross-sectional study is based on a single examination of a cross section of population at one point in time – the results of which can be projected on a whole population. Cross-sectional study is also known as “Prevalence study”.

(1) Setting:
A community-based approach was used after obtaining the sample size; the researcher conducted the study by visiting every tenth household of every tenth ward of Aligarh city. The information was recorded on a meticulously self-prepared and pre-tested questionnaire; which was used to examine the respondent and their parents respectively.

(2) Study population:
The study population included the children aged 6 – 9 years and their parents living in 1597 households

(3) Sampling frame:
The sampling frame was bound by the following inclusion and exclusion criteria.

INCLUSION CRITERIA –
a) Children aged 6 -9 years.
b) Permanent resident of Aligarh city, living permanently in Aligarh since birth.
c) Healthy children.
d) Both parents alive.

EXCLUSION CRITERIA:
a) Children living continuously outside Aligarh for a duration exceeding six months ever since their birth.
b) Non healthy children.
c) Pre - mature births.
d) Children whose mothers were exposed to radiation during pregnancy.
e) Children whose mothers had taken vaccination against Rubella/Varicella during pregnancy.
f) Children whose mothers were on long term medication during pregnancy.
g) All those not willing to participate in the study.

(4) Sampling method :-
Multi - layered sampling method (Stratified Random Sampling) was used. As being a multi - layered study, an attempt was made to differentiate the prevalence of oro – dental variations and oral health status in children born to parents with consanguineous and non - consanguineous marriages. In the first layer, it was assumed that the prevalence of consanguinity itself is around 20% in the study population. In order to reject the hypothesis that the prevalence of the most common oro – dental disease i.e. dental caries is different in children born to consanguineous parents, we required the sample size 5 times higher than the calculated sample size to precisely reach an equal number of children born to consanguineous parents.

The prevalence of the most common oro - dental disease i.e. dental caries in the general population at a targeted prevalence of 50%, the sample size was calculated using the following formula

\[ n = \frac{c^2 \times p (1-p)}{e^2} \]

n = calculated sample size
p = estimated prevalence (50% or 0.5)
c^2 = constant at 95% confidence limit and 80% power which equals to 1.96

\[ c^2 = \text{constant at 95% confidence limit and 80% power which equals to 1.96} \]

\[ e = \text{allowed error (as 5% or 0.05)} \]
Putting these values in the above equation

\[ n = 1.96^2 \times 0.5 \times (1 - 0.5) / 0.05^2 \]

\[ = 2.96 \times 0.25 / 0.0025 \]

\[ = 3.84 \times 100 \]

\[ = 384. \]

At 95 % confidence interval and 80 % power, the calculated sample size for the general population was 384. With the fact that consanguineous group forms only around 20 % of the total cross section, we required a sample size

\[ 384 \times 5 = 1920 \]

After adding for contingency, we went with a sample of 2000 (Annexure no.2).

In order to obtain the above calculated sample size in Aligarh city, which has 70 wards (Fig No.4) (Annexure no.3) and to ensure that each ward in the sampling frame has the chance of being selected, the wards were numbered; then a number was selected at random between 1 – 10. For this sampling; four was picked up and then every tenth ward was selected like 4,14,24,34,44,54,64 – which ended as 7 wards in total by systematic random sampling.

The same procedure was adopted for the selection of households by systematic random sampling. The selected ward no. 4, had 1505 number of households, out of which every tenth household was picked up which came out to be 150 households in ward no.4. The same procedure was adopted in the selection of households in the remaining selected six wards (156+481+143+247+306+114), which came out to a total of 1597 number of households in 7 wards. Where - ever in a house hold ,6 – 9 year old children were not available, the researcher moved on to the next house - hold located in the nearby.
(5) Assessment of age of the child :-

Majority of the parents produced the Birth certificates in support of age of the child. In few cases the age was determined in relation to the festivals (commonly used age determination pattern in India). Dentition at a particular age, also acted as a supportive adjunct.

(6) Permission and Clearances:-

Permission to carry out the study was obtained from the Institutional Ethics and Research Advisory Committee, Faculty of Medicine; Aligarh Muslim University, Aligarh (Annexure no.4). Informed Consent was obtained from all the parents of the respondents (Annexure no.5) and they were assured about the confidentiality of the information given by them.

(7) Tool for data Collection:-

To conduct a pilot study and to remove intra–observer bias, the information was recorded on a pre–designed questionnaire which was administered to 20 children. These 20 children were not included in the study sample. The study was conducted by a single examiner. Standardization and validity of the observer was done well before the conduct of the study.

The mean Kappa value was found to be 0.86. The overall internal reliability of the questionnaire was 0.74 according to Cronbach’s alpha. After testing and making the necessary corrections in the questionnaire used in the pilot study, the respondents and their parents were interviewed in depth and the data was recorded on a self prepared and now a pre–tested questionnaire (Annexure no.6).

The first part of the questionnaire dealt with the Demographic data like – Age, sex, religion, details regarding relationship between parents (consanguineous/non consanguineous marriage), type of consanguinity (first cousin/second cousin/third cousin), level of education of parents (Park & Park 2005), their occupation and birth order of the respondents.
The second part of the questionnaire dealt with the medical history and clinical – dental examination of the parents including molar relationship, incisal relationship and dental developmental defects. The third part respectively had the details of risk factors such as brushing frequency with or without paste, eating and drinking habits of the respondents (WHO Oral Health Questionnaire for children-5th Edition) \[103\]

The fourth and final part was used for a clinical – dental examination including molar relationship, incisal relationship and dental developmental defects like –fusion, gemination, non- syndromic supernumerary teeth, microdontia etc of the respondents. DMFT/deft index was recorded in accordance with the WHO Criteria for epidemiological studies using a sterilized mouth mirror and a CPI Probe by one investigator \[104\]. Oral examination was performed in natural light with children and their parents in supine position \[105\].

A tooth was diagnosed as carious when a lesion in the pit or fissure or smooth tooth surface had an unmistakable cavity, undermined enamel or a detectably softened floor or wall. A tooth with a temporary filling or one which was sealed but also decayed was included in the decayed category (D, d). Missing teeth (M, e) were those that had been extracted because of caries only, in case of missing primary teeth this score was used only in case the subject was at an age when normal exfoliation had not been a sufficient explanation for the absence. Filled teeth (F, f) were those which had been restored to keep them in a healthy condition. \[104\]

(8) Duration of the study:-

Two years i.e.7th March 2015 – 6th March 2017. The initial study period of 8 months was devoted to review the literature, conduct pilot study, protocol validation and assessment of pilot study for improvisations in study plan. A period of 12 months was used for data collection. The remaining study period of four months was used for data analysis and report writing.
(9) **Drawbacks of the Study:**

The study being a household survey, so radiographic examination was not possible. The absence of radiographic evaluation for the dental developmental anomalies and the age group inclusion criteria for the respondents as 6 – 9 years, may have acted as limitations for the present study in bringing out the actual presence and hence the association of dental anomalies in the study population with either of the groups. Information bias was also possible in the present research study, especially regarding disease reporting, as at times the parents might have misunderstood the question. Being a cross sectional study, it had the inherent drawbacks in the study design - it gave no idea about the aetiology, period prevalence and incidence rate.

(10) **Data Analysis:**

The questionnaire for the present was manually coded. A numeric was assigned to each variable. The data analysis was done by employing SPSS (Statistical Package for Social Sciences) Version 16 software. Following tests were calculated and a p value of <0.05 was considered significant:

(a) Descriptive statistics (frequency and percentages)

(b) Chi square test of significance and Fisher’s exact test.

(c) Mean Standard deviations (SD) and Student’s t-test.

(d) Multivariate logistic regressions (likelihood ratio test and parameter estimate)