4. MATERIALS AND METHODS

4.1. Pune division is one of the 6 divisions of Maharashtra state. It is bound by the Konkan division on the west side, Nashik division on the North side and Aurangabad division on the east side. On its south side it is bound by Karnataka state. It consists of 5 districts namely Kolhapur, Pune, Sangli, Satara and Solapur. It has a literacy rate of 77%.

The present study was carried out in select cities of the Pune revenue division of Maharashtra. (Fig 1)

All those Cities in the Pune revenue division of Maharashtra which had registered organ transplant centers or had a non transplant organ retrieval center (NTORC) were selected in this study. (Table 3)

| Registered Transplant centers and NTORCs | Pune, Karad, Sangli-Miraj, Kolhapur and Solapur |

Figure 1. Showing the 6 divisions of Maharashtra.
Institutes Ethical committee clearance was obtained before starting of the study. (Annexure 10.1)

The study was carried out in 3 parts, Part I, II, III.

4.2 Part I

Part I sought an insight into level of knowledge and awareness of 200 people regarding organ donation in the above mentioned cities, by administration of a questionnaire.

4.2.1 Inclusion and exclusion criteria:

The inclusion criterion for the study population was that all participants had to be residing in Pune revenue division of Maharashtra. They should be able to read and understand the form or should understand the form if it was read out to them. They should be above the age of 18 years. Only those consenting to participate were involved in the study.

The exclusion criterion was those who refused to consent to participate in the study.

The sampling method used here was convenience sampling.

Methodology-Part I

4.2.2 Pilot study, Preparation and validation of the questionnaire:

A specially designed self administered questionnaire covering demographic data, knowledge and attitude of the participants was prepared after consultation with related experts. 200 questionnaires were distributed for the pilot study out of which 50 random persons from Pune revenue division of Maharashtra consented to fill the questionnaire.

They were given a time period of 15 minutes for completion of the questionnaire wherein the respondents would indicate their responses to the questions using the categories provided in the questionnaire in privacy without any discussion with anyone. Consent of the participants was taken on Marathi or English consent forms as per their ease with language. (Annexure 10.2, A, B) The questionnaire was prepared in Marathi which is a language spoken in this region of India as well as in English. The respondents were given a choice of language according to their comfort level.

The researcher actively interacted with the respondents to discuss the problems in the questionnaire with them. The respondents were encouraged to think aloud and discuss the questionnaire filling with the researcher. The questionnaire was thus tested for clarity of the questions as well as time period required for response. Suitable modifications were made in the questionnaire and time span provided after discussion with experts and thus the questionnaire was validated. Finally the questionnaire was finalized. (Annexure 10.2, C, D)
4.2.3 Administration of the questionnaire:
Once the questionnaire was thus finalized it was administered to people residing in each of the 5 cities selected for the present study. About 800 forms were printed for each selected city in Marathi and English.

The methodology was explained to all the participants.

The respondents were assured that their confidentiality would be maintained and ethical principles would be followed. Those not willing to consent to participate were given the choice to withdraw from the study.

Written consent was obtained from each respondent in English or Marathi according to whichever language they felt comfortable in.

The pretested questionnaire was administered to the participants. The researcher actively interacted with the respondents to explain any terms in the questionnaire that they had difficulty in understanding. All explanations given were lucid, non coercive and non judgmental, made without influencing the respondents.

4.2.4 Tabulation of data and data analysis
The response sheets were collected. The data was tabulated by using Microsoft excel®.

The data received was in raw form. It was edited to make it more comprehensible.

Incomplete questionnaires or questionnaires filled by persons below the age of 18 years were discarded. The final data was analyzed statistically.

The doubts of the respondents were clarified after collection of the filled questionnaires in an informal discussion on the subject of organ donation. At times if requested a lecture was arranged on organ donation to create awareness and promote organ donation in the region.

Part II
The part II of the study investigated the challenges faced by medical care professionals in the field of organ donation. It consisted of two parts.

- **Part II-A**: This part of the study tried to investigate into the knowledge and attitude of medical care professionals in the field of organ donation. This was done by administration of a questionnaire.

- **Part II-B**: This part of the study consisted of detailed discussion with some doctors, nurses and organ transplant coordinators to bring out individual experiences of each specialty related to organ donation and problems encountered by them as they dealt with recipients and possible donors and their families. The doctors in this group
included surgeons, physicians, nephrologists, neurologists, intensivists, forensic medicine specialists, hepatologists, liver transplant surgeons, nurses working in ICUs and organ transplant coordinators.

**4.3.1 Inclusion and exclusion criteria for both Part II-A and Part II-B:**

The inclusion criterion for this study population was that all participants had to be medical care professionals residing in Pune revenue division of Maharashtra. Only those consenting to participate were involved in the study.

The exclusion criterion was those who refused to consent to participate in the study.

The sampling method used here was convenience sampling.

**Methodology-Part II-A**

**4.3.2 Pilot study and Preparation of the questionnaire:**

A specially designed self administered questionnaire covering demographic data, knowledge and attitude of the participants was prepared after discussion with experts in the field. 100 questionnaires were distributed for the pilot study out of which 50 medical care professionals from Pune revenue division of Maharashtra consented to fill the questionnaire. They were given a time period of 15 minutes for completion of the questionnaire wherein the respondents would indicate their responses to the questions using the categories provided in the questionnaire in privacy without any discussion with anyone. Consent of the participants was taken. The researcher personally interacted with the respondents to discuss the problems in the questionnaire with them. The respondents were encouraged to think aloud and discuss the questionnaire filling with the researcher. The questionnaire was thus tested for clarity of the questions as well as time period required for response. Suitable modifications were made in the questionnaire and time span provided after discussion with experts. Thus the questionnaire was validated.

Finally the questionnaire was finalized. (Annexure 10.2, E)

**4.3.3 Administration of the questionnaire:**

Once the questionnaire was thus finalized it was administered to medical care professionals residing in each of the 5 cities selected for the present study. About 200 forms were printed for each selected city.

The methodology was explained to all the participants.

The respondents were assured that confidentiality of identity would be maintained and ethical principles would be followed. Those not willing to consent to participate were given the option to withdraw from the study.
Written consent was obtained from each respondent. The pretested questionnaire was administered to the participants. The researcher personally interacted with the respondents to explain any terms in the questionnaire that they had difficulty in understanding. All explanations given were lucid, non coercive and non judgmental, made without influencing the respondents.

4.3.4 Tabulation of data and data analysis

The response sheets were collected. The data was tabulated by using Microsoft excel®. The data received was in raw form. It was edited to make it more comprehensible. Incomplete questionnaires were discarded. The final data was analyzed statistically. The doubts of the respondents were clarified after collection of the filled questionnaires in an informal discussion on the subject of organ donation. At times if requested a lecture was arranged on organ donation to create awareness and promote organ donation in the region.

4.4 Methodology-Part II-B

4.4.1 Inclusion and exclusion criteria

The Doctors, nurses and organ transplant coordinators residing and working in each of the cities in Pune revenue division of Maharashtra were requested for time to discuss challenges involved in process of organ donation in Pune revenue division of Maharashtra and they were requested to share their experiences in the field of organ donation. Only those who consented to participate in the study were included in the study.

The exclusion criterion was those who refused to consent to participate in the study.

The sampling method used here was convenience sampling.

4.4.2 Methodology and analysis

The respondents were assured that confidentiality of identity would be maintained and ethical principles would be followed.

The interviews were noted down during the discussion and the suggestions of the medical care professionals were noted. The discussions were immediately analyzed thereafter, for the themes generated during the discussions and for insights into the organ donation activity.

This qualitative research was done till the point of saturation.
4.5 Part III
This consisted of case studies of patients and their relatives in Pune revenue division of Maharashtra. The participants were classified into 4 categories:

1. Patients (and their relatives) waitlisted for an organ either from live or from a brain dead donor.
2. Recipient of an organ after transplant
3. Live organ donor and their relatives
4. Family members of a brain-dead organ donor

- **Inclusion and exclusion criteria for Part III**
The inclusion criterion for this study population was that all participants had to be either patients or relatives of patients residing in Pune revenue division of Maharashtra. Only those consenting to participate were involved in the study.
The exclusion criterion was those who refused to consent to participate in the study.
The sampling method used here was convenience sampling.

- **Methodology-Part III and analysis**
The discussions with the consenting participants were conducted in form of semi-structured individual interviews with a set of questions for each of the category of participants.
The respondents were assured that the confidentiality of identity would be maintained and ethical principles would be followed.
The participants were provided an overview of the purpose of the interview through a set of questions prepared both in Marathi and in English as per their ease with language. [Annexure 10.2, F, G, H, I (Marathi), J, K, L, M (English)]
The discussions were conducted at places where the participants felt comfortable. The experiences of the participants, the problems they encountered as well as factors that worked in favor of organ donation and advice and suggestions they may have for other donors, recipients and authorities were noted.
The interviews were noted down during the discussion and immediately thereafter and analyzed for emerging themes emerging that gave insights into the organ donation activity. This qualitative research was done till the point of saturation.
The summary of the Materials and Methods in short is depicted in Table 4.
Table 4. Methodology (in short)

<table>
<thead>
<tr>
<th>Part I</th>
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<td></td>
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<td>This consisted of case studies of patients and their relatives in Pune revenue division of Maharashtra. The participants were classified into 4 categories:   1. Patients (and their relatives) who are on the waiting list for an organ from either a live donor or a brain-dead donor.   2. Recipient of an organ after transplant   3. Live organ donor and their relatives   4. Family members of a brain-dead organ donor</td>
</tr>
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</table>