CHAPTER III:
RESEARCH METHODOLOGY

“Education is the most powerful weapon
you can use to change the world”

By- Nelson Mandela

The research methodology refers to a set of orderly discipline procedures involved in the deliberate collection, analysis and interpretation of the data. It includes Research approach, Research Design, Identification of Target, Sample, Sampling Technique, Sampling Size, Inclusive and Exclusive criteria of sample, Tool Preparation, Feasibility of the study, Validity Reliability Pilot study, and Data gathering process.

3.1) RESEARCH APPROACH:

Research approach is a systematic, objective method of discovery with empirical evidence and rigorous control. The control was achieved by holding conditions constant and varying with the phenomena under study.\(^3\)

The approach used in this study was descriptive evaluative approach. The researcher wants to describe the knowledge and practices of the nurses with regard to care of patient on ventilator in an intensive care unit before and after implementation of protocols. An evaluative approach enabled the researcher to identify the effectiveness of her protocols.

3.2) RESEARCH DESIGN:

Research design is the binding force that holds all the elements in a research together. A research design incorporates the most important methodological decisions that a research makes in conducting a research design

Pre experimental one group pre-test post test design was used in this study.

According to Nieswiadomy (2008) “Research design was used to indicate the type of study being conducted; these terms do not clearly indicate the study plan or specific design.”\(^71\)
Pre-experimental one group pre-test and post-test design was adopted for the present study. The one group pre-test post-test design provides a comparison between a group of subjects before and after the experimental treatment.

Table 3.1: Table showing Representation of the research design in the study

<table>
<thead>
<tr>
<th>Activities</th>
<th>Day One</th>
<th>Day 5,6,7 Observations Post-test P1,P2,P3</th>
<th>Day 29,30 31st Observations Average-Post test-P4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Knowledge Questionnaire on care of patient on ventilator</td>
<td>Pre-test- (90 min.)</td>
<td>Post-test-1 (60mins)</td>
<td>Post-test-2 (60mins)</td>
</tr>
<tr>
<td>Observation of practices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Handing over and taking over in intensive care unit.</td>
<td>on-going</td>
<td>on-going</td>
<td>on-going</td>
</tr>
<tr>
<td>2 Communication skills of nurse with the patient</td>
<td>on-going</td>
<td>on-going</td>
<td>on-going</td>
</tr>
<tr>
<td>3 Communication skills of nurse with the patient’s relatives</td>
<td>on-going</td>
<td>on-going</td>
<td>on-going</td>
</tr>
<tr>
<td>4 Performance of nurses in carrying out Endotracheal suctioning</td>
<td>15min.</td>
<td>10min x3 = 30 min</td>
<td>10min x3 = 30 min</td>
</tr>
<tr>
<td>5 Performance of nurses in changing of Endotracheal Tube Tie.</td>
<td>15min</td>
<td>10min x3 = 30 min</td>
<td>10min x3 = 30 min</td>
</tr>
<tr>
<td>6 Practices of nurses in maintaining oral hygiene of the patient on ventilator</td>
<td>15min</td>
<td>10min x3 = 30 min</td>
<td>10min x3 = 30 min</td>
</tr>
<tr>
<td>7 Practices of nurses in giving back massage and taking care of pressure points for the patient on ventilator</td>
<td>20min</td>
<td>15min x3 = 45 min</td>
<td>15min x3 = 45 min</td>
</tr>
<tr>
<td>8 Practices of nurses during enteral feeding for the patient on ventilator</td>
<td>15min</td>
<td>10min x3 = 30 min</td>
<td>10min x3 = 30 min</td>
</tr>
<tr>
<td>Reported Practices</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 Assisting in Endotracheal Intubation.</td>
<td>10 min</td>
<td>5 min</td>
<td></td>
</tr>
<tr>
<td>2 Monitoring patient on ventilator</td>
<td>10 min</td>
<td>5 min</td>
<td></td>
</tr>
<tr>
<td>3 Assisting in weaning the patient from ventilator</td>
<td>10 min</td>
<td>5 min</td>
<td></td>
</tr>
<tr>
<td>4 Assisting in Extubation</td>
<td>10 min</td>
<td>5 min</td>
<td></td>
</tr>
<tr>
<td>5 Assisting in ABG (Arterial blood gas) collection</td>
<td>10 min</td>
<td>5 min</td>
<td></td>
</tr>
<tr>
<td>Total time</td>
<td>220mins = ≥3hrs&amp;30 min + *</td>
<td>250 min = ≥4hrs</td>
<td>225 min = ≥3hrs &amp; 30 min</td>
</tr>
</tbody>
</table>

* = 2 hours teaching by researcher.
Assessed after five days only once.
The above research design shows that

Day one: - Pre-test on knowledge of nurses regarding care of patient on ventilator will be assessed using structured questionnaire. The time expected for the above pre-test will be 90.

This is followed by observation of practices in the area of Handing over and taking over in intensive care Unit, communication skills of nurse with the patient, communication skills of nurse with the patient’s relatives, performance of nurses in carrying out endotracheal suctioning, Performance of nurses in changing of Endotracheal Tube Tie, practices of nurses in maintaining oral hygiene of the patient on ventilator, practices of nurses in giving back massage and taking care of pressure points for the patient on ventilator, practices of nurses during enteral feeding for the patient on ventilator. All the practices mentioned will be assessed by the researcher using non participatory observations. One observation of each procedure. The duration will be one hour and 40 minutes.

Reported practices of Assisting in Endotracheal Intubation, Monitoring patient on ventilator, Assisting in weaning the patient from ventilator, Assisting in Extubation, Assisting in ABG (Arterial blood gas) collection will be assessed using inventory checklist. The time expected for the above procedure will be approximately 50 minutes.

Post-test on knowledge of nurses regarding care of patient on ventilator will be assessed will be assessed on day 5th and day 30th and the time expected will be 60 minutes.

Post-test practices in the above area will be assessed on day five to day seven post-test P1, P2, P3 will be three observations and the duration will be approximately 3 hours and 25 minutes. Similarly on day 29th to 31st day observational practices will be assessed three time each procedure and the average of three will be considered as P4 and the duration will be approximately 3 hours and 25 minutes as above.

Procedures included in the Inventory checklist will be reported by the nurse from day 5 to day 7 only once and the duration will be 25 minutes. The procedures included in the inventory checklist is done on an emergency basis and direct observation of the same may not be possible in an emergency situation as the researcher planned to remain in the area for a duration of 12 hours. Since reported practices will be marked by the nurses it will be assessed after 30th day. Keeping in mind one of the drawback of reported practices i.e. the authenticity in reporting.
Identification of research problem on nursing care of patient on ventilator, procedures that should be focused in order to prevent complication and its effect on recovery.

Review of literature, visiting different ICU'S, meeting experts for guidance.

Seeking permission from the Director of DMER. Development of research tool, approval from ethical committee and permission from all hospital authorities.

Selection of samples, seeking consent, self-introduction.

Day one - Delivering pre-test for knowledge assessment, observation of practices, introduction of protocols and teaching.

Day five - Assessment of knowledge as Post-test-1
Day five, six and seven reported practices once as post-test-1 and observation of practices three times each observational checklist as post-test-P1, P2, P3

Day 30th - Assessment of knowledge as Post-test-2
Day 29, 30, 31st three observations of each procedure average as post-test-P4

Analysis of the data, presentation of tables, testing hypothesis.

Conclusions and recommendations.
### Table - 3.2: Plan for data collection, setting date and No. of Samples.

<table>
<thead>
<tr>
<th>Regions</th>
<th>Name of the hospital</th>
<th>Area</th>
<th>Date To &amp; From</th>
<th>No. of nurses studied</th>
</tr>
</thead>
<tbody>
<tr>
<td>PUNE</td>
<td>C. P. R., Hospital Kolhapur</td>
<td>INTENSIVE CARE UNIT</td>
<td>21/1/2013 to 22/3/2013</td>
<td>11</td>
</tr>
<tr>
<td>AURANGABAD</td>
<td>G. M. C. &amp; Hospital, Latur</td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>SRTR. Hospital Ambejogai</td>
<td></td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>PUNE</td>
<td>C.S.M Govt. Hospital, Solapur</td>
<td></td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>NASHIK</td>
<td>Bhausaheb Hire. Govt. Hospital. Dhule</td>
<td></td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>AURANGABAD</td>
<td>Ghati Hospital, Aurangabad.</td>
<td></td>
<td>25/3/2013 to 11/5/2013</td>
<td>32</td>
</tr>
<tr>
<td>NAGPUR</td>
<td>G.M.C.&amp; Hospital Nagpur- Nagpur-IGMC</td>
<td></td>
<td>13/5/2013 to 17/8/2013</td>
<td>22</td>
</tr>
<tr>
<td>AMRAVATI</td>
<td>G M C &amp; Hospital, Yewatmal G M C &amp; Hospital, Akola</td>
<td></td>
<td></td>
<td>09 12</td>
</tr>
<tr>
<td>KONKAN</td>
<td>G.T Hospital. Mumbai St, George Hospital. Mumbai J.J Hospital. Mumbai</td>
<td></td>
<td>19/8/2013 to 29/9/2013</td>
<td>14 16</td>
</tr>
<tr>
<td>PUNE</td>
<td>Sassoon General Hospital, Pune</td>
<td></td>
<td>30/9/2013-31/10/2013</td>
<td>19</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td></td>
<td></td>
<td>220</td>
</tr>
</tbody>
</table>

### 3.3) VARIABLES OF THE STUDY:

Variables are qualities, properties or characteristics of a person, thing or situation that changes or vary. Polit & Beck (2008).

Based on the objectives of the study, the major variables are identified.

A) **Independent Variables:**
According to Burns & Groves (2007), “An independent variable is a stimulus or activity that is manipulated or varied by researcher to create an effect on the dependent variable.”

In this study the Independent Variable is the developed standard operating protocols.

B) **Dependent Variables:**

According to Burns & Groves (2007), “It is the outcome or response that the researcher wants to predict or explain.”

In this present study, the dependent variables were

i. The knowledge of the nurses regarding care of patient on ventilator.

ii. The practices of the nurses in relation to care of patient on ventilator

C) **Demographic Variables:**

According to Nieswiadomy, (2008) these are subject’s characteristics.

In the present study age, gender, educational qualification, and years of experience were the demographic variables

3.4) **THE SETTING OF THE STUDY:**

According to Wood & Kerr (2006) “Setting refers to the area where the study is conducted.”

The study was conducted in 14 government hospitals from six regions of Maharashtra governed by Directorate of Medical Education. (Fig-2)
The six regions of Maharashtra were Konkan, Nashik, Pune, Aurangabad, Amravati and Nagpur and the 14 hospitals were:

- Konkan region: - Gokuldas Tejpal Hospital (G.T.) Hospital, St. George Hospital and J.J.Group of Hospitals Mumbai
- Nashik region: - Bhausaheb Hire Govt. Hospital Dhule.
- Pune region: - Chatrapati Pramila. Raje. (CPR) Hospital Kolhapur, Chatrapati Shahu Maharaj (C.S.M) Govt. Hospital, Solapur. Sassoon General Hospital, Pune
- Aurangabad region: - Govt. Medical. College.(G.M.C.) & Hospital, Latur, Shri Ramanad Tirth Rural (SRTR). Hospital, Ambejogai and Ghati Hospital. Aurangabad.
- Amravati region: - Govt Medical College & Hospital, Yewatmal, Govt. Medical College & Hospital Akola.
- Nagpur region:- Govt. Medical .College & Hospital Nagpur and Indira Gandhi Govt. Medical College(I.G.M.C) & Hospital Nagpur.
All these 14 hospitals were well renowned hospital situated in the important major cities of Maharashtra were Medical Education and research is conducted. Bed strength of the hospitals ranged from 500 to 1500. ICU beds in each hospital were 10 to 12 and the intubated patients were six to eight. Most of the patients getting admitted were tertiary care patients. The turnover of the patients getting admitted in the intensive care unit is very high and the economical condition of these patients being admitted is also low.

The nurse patient ratio over Maharashtra in all regions was 1:4 to 1:5 in morning shift while in evening and night the ratio was 1:5 to 1:6

3.5) POPULATION:
According to Polit and Beck (2008) “The population is a complete set of individual or objects that possess some common characteristics of interest to the researcher”. In this study

A. Target population:
According to Polit and Beck (2008) “Target population or universe is composed of the entire group of people or objects, to which the researcher wishes to generalize the findings of the study.”

In this study the target population, were the nurses working in the intensive care units of all the government hospitals under Director of Medical Education. The total numbers of nurses working in this area from all six regions were 250.

B. Accessible population:
According to Polit & Beck (2008) “Accessible population is the aggregate of participants who conform to the designated criteria and are accessible as a pool of subjects for the study.”

The accessible population for the study was the nurses working in the intensive care units, who were available at the time of study. The total numbers of nurses were 220, excluding the samples (22 nurses) involved in the pilot study

3.6) SAMPLE:
According to Nieswiadomy, (2008) “Sample is a subset of the population that is selected to represent the population. In other words, sample consists of a subset of unit which comprises the population selected by researchers or researcher to participate in their research project.” In this study samples consisted of nurses of working in intensive care units of 14 hospitals from six regions governed by DMER, who fulfilled the inclusion criteria.

3.6.1) Sample size :

The estimated sample size for the study is determined largely by three factors:

(i) The estimated prevalence (P) of the variable of interest - for this study prevalence of knowledge of nurses on care of patient on ventilator in ICU was 50.11 % (H.Perrie and Schmollgruber 2010)

(ii) The desired level of confidence – for this study taken as 95%

(iii) The power – 80%

(iv) Absolute precision / Acceptable Error (E) – 5%

Mean Knowledge score of ICU trained staff = 50.11 with SD = 11.96 (Ref. 1)

Confidence level = 95%

Power = 80%

Error = E = 5% of mean = 5% of 50.11 = 2.5055

\[
N = \frac{(Z\alpha + Z\beta)^2 \times SD^2}{E^2}
\]

\[
= \frac{(1.96 + 0.84)^2 \times (11.96)^2}{(2.5055)^2} = 178.64 = 179
\]

Here

\( Z\alpha = 1.96 \) for confidence level of 95%

\( Z\beta = 0.84 \) for power 80%

SD = Standard deviation

E = Error

N = Sample Size

Attrition rate = 20% of n = 35.80 = 36

n = 179 + 36 = 215

So the sample size in the study was 220 staff nurses working in ICU of 14 hospitals.
3.6.2) Criteria for selection of sample: Eligibility criteria are the characteristics that delimit the population of interest (Polit and Hungler 1999).\(^77\)

A. Inclusion criteria:
Nurses who were –
  i. Working in the intensive care units for more than three months and directly involved in patient care.
  ii. Willing to participate in the study.

B. Exclusion criteria:
Nurses who were –
Working in the intensive care units but were not directly responsible for patient care i.e. Head nurses.

3.7) SAMPLING TECHNIQUE:

According to Fain (2008) “It refers to the process of selecting a portion of the population to represent the entire population.” In this study Non probability purposive sampling technique is used. In purposive sampling, the researcher believes that some subjects are fit for research compared to other individuals. This is reason why they are purposively chosen as subjects. Purposive sampling design is usually used when a limited number of individuals possess the trait of interest. It is the only viable sampling technique in obtaining information from a very specific group of people.\(^78\)

In this study six regions(divisions) in which Maharashtra is divided are - Konkan, Nashik, Pune, Aurangabad, Amravati and Nagpur in these regions the hospitals under Directorate of Medical Education and Research. (DMER) were identified and the nurses working in those hospital in the intensive care unit were selected according to the map given.(Fig-3.2).
3.8) **TOOL AND TECHNIQUE FOR DATA COLLECTION:**

**Tool:**

The development of the tool was a step by step procedure, for which the researcher adopted a practical approach.\(^7^9\)

Prior to the preparation of the tool researcher studied the different aspects of nursing care for the patient on ventilator and the complications that can occur in the patients on ventilator due to inadequate nursing care. Researcher also studied about various ventilators, its modes, weaning process.

The researcher visited various hospitals; ICU’s and interacted with the Intensivists, doctors, and nurses working in ICU. She also took the feedback from the patients who were on ventilator, so that she could get some insight into the topic for preparation of tool.

The researcher also interacted with State Nursing Superintendent of Maharashtra, Matrons. Sisters Incharge and staff nurses of different hospitals and assessed feasibility of conducting the study and their administrative help to do so. The development of tool was processed .The researcher updated her knowledge on procedure conducted in ICU, newer approach in communication, new techniques used in procedures like suctioning, monitoring, weaning, patients on ventilator.

The researcher discussed about the protocols to be developed with various experts in the related field that is Intensivists, doctors, senior nursing personnel worked and working in ICU and incorporated their valuable suggestions.

The researchers own knowledge and experience, expert’s suggestions and review of literature helped in preparation of the tool. Duration of three months was required for preparation of the tool

Keeping the objectives of the study in mind and expert’s suggestions the researcher selected the following as her tools for data collection.

2. Teaching Module
3. A structured knowledge questionnaire.
3.8.1) **Development of standard operating protocols:**

The steps adopted in the development of Standard operating protocols.

Researcher searched for the available protocols in government hospitals it was found that no such protocols existed. Guidelines from private hospitals, online search, review of books, journals and intensive review of literature was done. Evidence based practices were considered in development of protocol. Matter was collected and framed accordingly from the available material and preparation of final draft was prepared. 13 protocols were prepared based on priority and feasibility to care a patient on ventilator. Validation of the protocols was done by a committee of six experts in the intensive care units and one expert in medical surgical nursing. The Panel was formed by the ethical committee. Out of six experts three were internal members of Dept. of medicine, surgery and anaesthesia from government hospital while other three members were the directors of Intensive care units among one of the three major private hospitals in Pune city. Total 17 protocols were prepared out of which four were deleted due to the common agreement by the experts. (Refer annexure-N & O) There was 90% agreement from the expert’s regarding the protocols. This process helped the researcher in achieving the first objective. The developed protocols were given to the nurses in the study protocol was given to staff nurses after pretest and teaching.

Content of the protocols was as follows.

- a. Handing over and taking over at the change of shift
- b. Communication in the ICU by nurses with patient on ventilator
- c. Communication by nurses with Relatives or significant others.
- d. Assisting for Intubation of the patient
- e. Monitoring the patient on ventilator
- f. Suctioning of endotracheal tube
- g. Assisting for Arterial blood gas collection and its interpretation
- h. Change of twill tape
- i. Care of mouth
- j. Back massage and care of pressure points.
k. Enteral feeding of patient on ventilator 

l. Protocol for Assisting for Weaning off from ventilator 

m. Protocol for Assisting for Extubation of the patients. 

From the above 13 protocols, protocol ‘a’ was not included in the knowledge questionnaire because it was more on psychomotor domain than cognitive domain. Protocol ‘b’ and protocol ‘c’ on Communication in the ICU by nurses with patient on ventilator and Communication by nurses with Relatives or significant others work clubbed together as one in the knowledge questionnaire. Protocol ‘d’ and protocol ‘h’ Assisting for Intubation of the patient and Change of twill tape clubbed together as one in knowledge questionnaire. Thus bringing the total areas of knowledge questionnaire into ten sub sections.

For details of protocols and reference refer annexure (A)

3.8.2) Development of teaching module

The draft of teaching module was done on the basis of literature review on, procedure done in intensive care unit and the knowledge of nurses in an ICU, their deficiencies and requirement. Evidence based practices were considered during the development of the teaching module. The studies reviewed helped in modifying the teaching plan. The plan was developed and given for validation. The module was modified according to the suggestion of the experts. Following were the Objectives of the teaching module:

The Group will be able

a. To maintain routine work in Intensive Care Unit.
b. To communicate with the patients and relatives in the I.C.U. and meet the informational needs of the relatives.
c. To assist in endotracheal intubation, Extubation and change of twill tape of the patient on ventilator.
d. To monitor patient on ventilator and to assist in weaning the patient from ventilator.
e. To carry out endotracheal suctioning.
f. To meet hygienic needs of the patient by
   i. maintaining oral hygiene of the patient on ventilator
   ii. Giving back massage and taking care of pressure points for the patient on ventilator.
g. To assist in ABG (arterial blood gas) collection to be able to interpret the report.

h. Meeting the nutritional needs of the patient.

The time required for teaching was two hours. For details of teaching module refer annexure (B)

3.8.3) Development of Structured Knowledge Questionnaire for:

Questions were prepared with the help of references from the books and articles. A blueprint was prepared and the content was organized under the following heading.

Structured questionnaire based on knowledge regarding care of patient on ventilator was developed with two sections.

Section I: -Socio demographic data of Nurses (Age, gender, educational qualification and years of experience in ICU)

Section II: -Knowledge questionnaire based on care of patient on ventilator. This section was divided into 10 sub sections - A and J. Total score of this section was 75 with one correct answer. Questions were in relation to assessment of knowledge of nurse regarding care of patient on ventilator. In a questionnaire each correct answer was given a score of one and a wrong answer was given a score of zero. The duration for answering the questionnaire was 90 minutes.

A) Questions related to Communication in ICU with patients and relatives.
   (6 Questions)
B) Questions related to Assisting for Intubation and change of twill tape :
   (11 questions)
C) Questions related to Extubation of the patients :
   (6 Questions)
D) Questions related to Monitoring the patient on ventilator :
   (6 Questions).
E) Questions related to Assisting for Weaning off the patient from ventilator :
   (5 Questions)
F) Questions related to Suctioning of Endotracheal tube :
(9 Questions)

G) Questions related to Arterial blood gas collection and its Interpretation: (8 Questions)

H) Questions related to Oral hygiene of the patient on ventilator: (6 Questions)

I) Questions related to back massage and care of pressure points: (9 Question)

J) Questions related to Enteral feeding to a patient on ventilator: (5 Question)

The structured knowledge questionnaire had 75 questions with one mark for each correct answer. The cumulative score was converted into percentage and was arbitrarily graded as follows.

The score was interpreted in the following manner.

0-18 score - 0-25% (P=Poor),

19-37 score -26-50% (A-Average),

38-56score-51-75% (G-Good),

57-75 score -76-100% (Ex-Excellent).

3.8.4) **Observation check list**:

The purpose of the Observation checklist was to record the practices of nurses in the aspects of caring the patient on ventilator. Out of 13 protocols Observation of eight procedures was done with the help of checklists as these were the routine procedure which needs to be carried out by the nurse on regular basis which were as follows.

a. Maintaining routine work in Intensive Care unit that is handing over and taking over in intensive care unit. Total score - 20

b. Communication skills of nurse with the patient. Total score - 14

c. Communication skills of nurse with the patient’s relatives. Total score - 14


Practices of nurses in maintaining oral hygiene of the patient on ventilator. Total score - 22

Practices of nurses in giving back massage and taking care of pressure points for the patient on ventilator. Total score - 22

Practices of nurses during enteral feeding for the patient on ventilator. Total score - 18

Each procedure was observed individual checklist. Each checklist had steps of the procedure in the statement form at left hand side and yes no column at right hand side. Whenever a particular nurse carried out the procedure a ‘✓’ mark was put in the column ‘Yes’ and when a particular procedure was not performed a ‘X’ mark was put against that item. The ‘✓’ mark was given a score of one and a ‘X’ mark was given a score of zero.

Three observations of same procedure was done between 5 to 7 days (Post-test P1, P2, P3) after implementation of protocol and teaching module. While the average score of three observations was considered after 29,30th and 31st day. (P4).

The total number of items of the eight observation checklists had a score of 180. Each correct step was given a score of 1. Individual observed practice score for over all checklist was arbitrarily graded as follows.

For details of Observation check list refer annexure (F)

The score was interpreted in the following manner.

<table>
<thead>
<tr>
<th>Score</th>
<th>Percentage</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 45</td>
<td>(0-25%)</td>
<td>Poor</td>
</tr>
<tr>
<td>46 – 90</td>
<td>(26-50%)</td>
<td>Average</td>
</tr>
<tr>
<td>91 – 135</td>
<td>(51-75)</td>
<td>Good</td>
</tr>
<tr>
<td>136 – 180</td>
<td>(75-100%)</td>
<td>Excellent</td>
</tr>
</tbody>
</table>

3.8.5) An Inventory check lists :  
The area which was found difficult to directly observe was assessed with the help of reported practices by the Inventory checklists. Reported practices were elicited in the following areas.

a. Assisting in Endotracheal Intubation. Total score- 44

b. Monitoring patient on ventilator. Total score- 24

c. Assisting in weaning the patient from ventilator. Total score- 30

d. Assisting in Extubation. Total score- 34
e. Assisting in ABG (Arterial blood gas) collection. Total score- 22

Each of the reported practices was observed using inventory checklist. Each checklist had steps in the form of statements at the left hand side and ‘yes’ ‘no’ column at right hand side. Whenever a particular nurse carried out the step she had to mark (‘✓’) in the column of ‘Yes’ and when a particular step was not done a (‘X’) mark was put against that item by her. The ‘✓’ mark was given a score of one and a ‘X’ mark was given a score of zero. The score of the five inventories checklist was 154. Reported practice was assessed once between 5 to 7 days. The cumulative score was converted into percentage and arbitrarily graded as follows.

<table>
<thead>
<tr>
<th>Score Range</th>
<th>Grade</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 38</td>
<td>Poor</td>
<td>(0-25%)</td>
</tr>
<tr>
<td>39 – 76</td>
<td>Average</td>
<td>(26-50%)</td>
</tr>
<tr>
<td>77 – 115</td>
<td>Good</td>
<td>(51-75%)</td>
</tr>
<tr>
<td>116 – 154</td>
<td>Excellent</td>
<td>(76-100%)</td>
</tr>
</tbody>
</table>

Individual checklist was also graded as 0-25% poor, 26-50% average, 51 to 75% good and 76 to 100% excellent.

For details of Inventory check list refer annexure (G)

Table - 3.3: Arbitrary scoring key for over all practice
( Observation checklist+ Inventory )

<table>
<thead>
<tr>
<th>Score Interpretation for over all practice ( Observation checklist+ Inventory )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
</tr>
<tr>
<td>-------</td>
</tr>
<tr>
<td>0-83</td>
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<td>84-166</td>
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<td>167-250</td>
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<td>251-334</td>
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3.9) **Validity of the tool**

Validity is defined as the degree to which an instrument measures what it is expected to measure.

a. **Validity of protocol –**

Validation of the protocols was done by a committee of six experts in the intensive care units and one expert in medical surgical nursing which was decided & formed by ethical committee. Out of six experts three were internal members of Dept. of medicine, surgery and anaesthesia in Sassoon General Hospital while other three members were the directors of Intensive care units among one of the three major private hospitals in Pune city. Total 17 protocols were prepared out of which four were deleted as per the suggestions of the experts. (Refer annexure-N & O) There was 90% agreement among the expert’s regarding the items listed in the protocol.

b. **Validity of the questionnaire-**

Validity of questionnaire was done by 10 experts from various fields in nursing. There were 125 questions in the beginning out of which 40 were deleted which were based on the above four protocols that were deleted during validation and 10 questions by the common agreement of the experts.

c. **Validity of the Inventory checklist, observation checklist and the teaching module**

It was scrutinized and validated by 10 experts in Nursing. There was common agreement about the items in the tool. Only few negligible additions and deletions were made in the Inventory checklist, observation checklist and the teaching module. Some of the items were reframed for better clarity.

3.10) **RELIABILITY :**
“Reliability refers to the consistency with which an instrument or test measures whatever it is supposed to measure. The more reliable a test or instrument, the more a researcher can rely on the scores obtained to be essentially the same scores that would be obtained if the test re-administered.”

In order to measure the reliability of the questionnaire, the test–retest method was used. The knowledge Questionnaire was administered to 22 nurses from one of the government hospitals, which were excluded from the actual study. The total score of knowledge obtained was calculated by Cronbach $\alpha$.

The co-efficient of reliability for the question statement was calculated by using formula given below for all the parts of section II i.e. knowledge regarding care of patient on ventilator.

\[ \text{Formula used for it was:-} \]

\[ \text{Cronbach } \alpha = \frac{n}{n-1} \left( 1 - \frac{\sum \sigma_i^2}{\sum \sigma_0} \right) \]

The value of ‘r’ obtained was 0.80 which was above the normal value of 0.7. Thus the tool structured questionnaire was found reliable statistically.

Reliability for the observation check list was tested by ‘Inter Rater Reliability Test’ in one of the selected hospitals. Two of her colleagues observed five nurses, using the observation check list.

The reliability of the observation checklist and inventory checklist was established by using Scott ¶ formula.

\[ \text{Scott } \parallel = \frac{100 - \Sigma D - \Sigma E^2/100}{100 - \Sigma E^2/100} \]

The statistical analysis computed had relation of range from 0.82 to 0.99 in all the 13 checklists using the above formula which indicated the high reliability of the tool.
Reliability of knowledge questionnaire was 0.90.

Reliability of Observation checklists is as follows

1. Maintaining routine work in Intensive Care unit that is handing over and taking over in intensive care unit. = 0.95
2. Communication skills of nurse with the patient = 0.82
3. Communication skills of nurse with the patient’s relatives = 0.82
4. Performance of nurses in carrying out Endotracheal suctioning = 0.99
5. Performance of nurses in changing of Endotracheal Tube Tie. = 0.99
6. Practices of nurses in maintaining oral hygiene of the patient on ventilator = 0.94
7. Practices of nurses in giving back massage and taking care of pressure points for the patient on ventilator = 0.85
8. Practices of nurses during enteral feeding for the patient on ventilator = 0.84

Reliability of Inventory checklists is as follows:

1. Assisting in Endotracheal Intubation. = 0.94
2. Monitoring patient on ventilator = 0.90
3. Assisting in weaning the patient from ventilator = 0.87
4. Assisting in Extubation = 0.87
5. Assisting in ABG (Arterial blood gas) collection. = 0.99

3.11) PILOT STUDY:

A pilot study is a smaller version of the proposed research study, conducted to revise and refine the data collection process, the treatment, interventions or the research tool. ⁷⁹

According to Polit and Hungler, Pilot study is a small scale version or trial run, it is done in preparation for a major study. ⁷⁷

The purpose of the pilot study was

a. To make improvements in the research project and secondly
b. To detect problems that must be counter checked and eliminated before the major study is attempted.
Pilot study was conducted from 15th December 2012-19th January 2013 at Miraj Medical hospital and Sangli Civil Hospital. Before starting the pilot study necessary permissions from the Ethical committee, Director DMER, Dean, Matron and Head of the Department of each hospital were taken. Total of twenty two nurses, eleven from Miraj and eleven from Sangli hospital were selected as per sampling criteria laid down. Purpose of the study was explained, their written consent was taken, and the pretest questionnaire was given to them to fill up. The filled questionnaire was returned to the researcher by the nurses in one hour to one and half hour (90min). In the later part of the morning and afternoon the same nurses were observed for their practices and recorded in the observational checklist by the researcher. The nurses were also given inventory checklist on duty they were taught how to fill up and completed after they did the procedure. The nurse who were given pretest previous day were given the protocols as well as teaching on the second day, skills were also demonstrated. Post test was given after fifth day of teaching and one month of teaching. Each nurse was observed three times consequently for her practices for the same procedure to check the consistency in her work.

The Pilot study helped the researcher to visualize some of the practical problems and also gave her better insight for the study. Initially the researcher had included Arterial blood gas collection procedure in the observation checklist but since procedure was done only in emergency in most of the hospitals it was included in the inventory checklist.

3.12) DATA GATHERING PROCESS:

Data gathering process began from 21/1/2013 and ended on 31/10/2013
Before starting the data permission researcher obtained permission from Director D.M.E.R., State Nursing Superintendent (SNS) and the ethical committee approval. Later researcher took permission from the Dean, Matron and Head of the Department of each hospital and also the sister in charges of each ICU. Permission for staying in the hostel in each hospital was granted by SNS and matrons of the respective hospitals. (For details of ethical approval and permission letters refer (annexures H to L).

Researcher grouped the hospitals of adjoining areas into one group based on there accessibility for the study. The hospitals were visited as per the planned schedule.(table-3.2 ) Researcher reached the hospitals one day before and acquainted herself in the hostel. Permission to stay in the hostel was taken so that the researcher could collect the data in all
the three shifts. 7.30 am to 11 pm. Data was collected from Monday to Saturday if the target for data collection was not achieved even Sundays were included.

On the day one the researcher met the matron in her office at 7.30 am. Matron introduced the researcher to the ICU sister in charge and asked her to make the nurses available for the study. SNS had directed the matrons to keep the nurses ready for pre-test hence maximum nurses were available on day one for the pre-test. Researcher went with the matron in the ICU, introduced herself to the staff of the ICU and explained them about the purpose of the visit and the role of the nurses in the study. Researcher oriented herself to the ICU at 10 am went to meet the Dean of the hospital and HOD the department along the matron. 12 noon the nurses were assembled in the lecture hall at the side of ICU. The sitting arrangement was made for them to write the test written consent was taken from the nurses, and the structured knowledge questionnaire on care of patient on ventilator was given to the nurses and the pre-test was conducted. Supervision was done by the researcher herself. The filled questionnaire was returned to the researcher by the nurses in 90 minutes. The nurses who gave pre-test were observed for their practices once and recorded. Each observation took 15-20 minutes. After the pre-test and observation of practices they were given teaching, skills were demonstrated and set of protocols was given to them. Teaching of two hours with demonstration of skills was done in the morning hours 10 am to 12 Noon for the nurses who had afternoon shift, night shift and day offs. While teaching for morning shift nurses was done in the afternoon 2 pm-4 pm. Pre-test and teaching was completed in first two-three days. The nurses on duty were given inventory checklist and how to fill up. The inventory checklist was filled by the nurses after they completed the procedure this took 10 minutes to fill each inventory checklist. Nurses were informed about post-test on day five and day 30th for knowledge assessment. They were also informed that the practices regarding care of patient on ventilator of each nurses will be observed by the researcher, each procedure that is taught will be observed three times.

Post-test-1 for knowledge was given on day five (60 minutes). in the similar manner. Practice of the inventory checklist were also reported by the nurses from day five to day seven as post-test-1. Each nurse was observed by the researcher three times consequently for her practices for the same procedure to check the consistency in her work between day five to day seven which was mentioned as post-test P1, P2, P3.

Post-test-2 for knowledge were given on day 30th. Each nurse was observed by the researcher from day 29 to day 31st three times for the same procedure and the average score of three was considered as P4. Observations were done 7.30 am to 11 pm.
Termination of the study was done by thanking the Dean, HOD of the dept. Matron, sister incharge and staff nurses who participated in the study. Contamination of the data was avoided by the researcher by supervising the nurses during the test. No questionnaire was given to the nurses out of the hall. The above process of data collection was done in all 14 hospitals till the sample size as completed. By following the planned schedule the researcher completed data gathering in the given time.

3.13) **PLAN FOR DATA ANALYSIS:**

It was planned to analyze the data according to the objectives.

a. The sociodemographic data will be calculated by using frequency percentage.

b. The knowledge of the nurses regarding the aspects of care of patient on ventilator was calculated by using frequency percentage.

c. The comparison between pre-test and post-test knowledge and practice scores will be assessed by using Wilcoxon test.

d. The association of knowledge and practices with sociodemographic data of the nurses of all six different regions will be calculated by using Chi-square.

e. The correlation between the knowledge and practices of the nurses will be calculated by using co-efficient of correlation.