### CHAPTER III
**RESEARCH METHODOLOGY**

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CHAPTER III

RESEARCH METHODOLOGY

“It appears at first incredible that any discovery should be made, and when it has been made, it appears incredible that it should so long have escaped men’s research. All of which affords good reason for hope that a vast mass of inventions yet remains”.  
– Francis Bacon

Research methodology is a systematic way to solve a problem. It is a science of studying how research is to be carried out. Essentially, the procedures by which researchers go about their work of describing, explaining and predicting phenomena are called research methodology. It is also defined as the study of methods by which knowledge is gained. Its aim is to give the work plan of research.¹

This chapter deals with the research approach, research design, setting of the study, selection of samples, sampling technique, construction of the tools, techniques used, testing of the tools, pilot study, data gathering process and plan for data analysis.

3.1 RESEARCH APPROACH

Research approach involves the description of the plan to investigate the phenomenon under study.² When conducting research, it is necessary to determine which approach is being implemented, because ‘scientific inquiry in practice typically involves alternating between deduction and induction’. Research approaches can be divided into two categories deductive approach and inductive approach. If the researcher adopts a hypothesis, the research is aimed to explore, then it will be deductive approach. The relation of hypothesis to the study can serve as the main point of difference between these two approaches. It has been noted that two important functions that hypothesis serve in scientific inquiry are development of theory and the statement of parts of an existing theory in testable form.³
In this study the researcher used a deductive approach, as the study aimed to find out the effect of a self instructional module on knowledge and practice in relation to selected aspects of communication of nurses.

3.2 RESEARCH DESIGN

“A well designed study, poorly analyzed, can be rescued by re-analysis but a poorly designed study is beyond the redemption of even sophisticated statistics”

A research design is a blue print for conducting a study. The research design of a study spells out the basic strategies that researcher adopts to develop evidence that is accurate and interpretable. Research design comprises of decision regarding What? Where? When? How much? By what means? concerning an inquiry or a research study.

Quantitative designs tend to be fairly structured. The researcher specifies the nature of intervention, comparisons to be made, methods used to control extraneous variables, timing of data collection, study site and setting and information to be given to participants, all before a single piece of data is gathered. Quasi experiments, like true experiments involve manipulation of an independent variable, that is an intervention. Quasi experiments however lack either the randomization or control group feature that characterizes true experiments. In quasi experimental studies, the researcher develops an intervention that is expected to result in differences in post test measures. In one group pretest – posttest, a pretest observation of the dependent variable is made before implementation of the intervention and finally a posttest observation is undertaken to find out the effectiveness of the intervention. A quantitative study using quasi experimental design with one group pre test post test design was initiated, since the study was to find out the effect of a self instructional module (Independent variable) on knowledge and practice (dependent variable) in relation to selected aspects of communication of nurses.

<table>
<thead>
<tr>
<th>Pre test</th>
<th>Intervention</th>
<th>1st week</th>
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<tr>
<td>K₁ + O₁</td>
<td>I</td>
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K denotes knowledge, O denotes observation of practice and I denote intervention.
3.2.1 SCHEMATIC REPRESENTATION OF THE RESEARCH STUDY IS PRESENTED IN FIGURE 2

Identification of problem

Review of Literature

Development, validation and printing of research tool i.e. self instructional module, structured questionnaire, structures observation checklist, opinionnaire, patient satisfaction feedback, SBAR format, Audit checklist

Obtaining permission from Institutional Review Board

Observation of hands off and admission process, administration of pre test

Distribution of self instructional Module

Post test

Knowledge, Practice, SBAR audit, Opinionnaire, Patient feedback

Conclusion, Recommendations, Nursing Implication

Data Analyses and Interpretation, testing of hypothesis

Conclusion and Recommendations
3.3 VARIABLES

Variables are qualities, properties or characteristics of persons, things or situations that change or vary. An independent variable is a stimulus or activity that is manipulated or varied by the researcher to create an effect on the dependent variable. The independent variable is also called as treatment or experimental variable. A dependent variable is the outcome or response that the researcher wants to predict or explain.\(^5\)

Independent variable: In this study the independent variable is the self instructional module which was given to the nurses regarding clinical communication skills.

Dependent variable: In this study, the dependent variable is the knowledge and practice of nurses with regard to selected aspects of communication. The selected aspects are verbal, non verbal, communication skills and documentation.

The effect of the independent variable on dependent variable was studied.

3.4 SETTING OF THE STUDY

The Advanced Centre for Treatment, Research and Education in Cancer (ACTREC) is the state-of-the-art R&D satellite of the Tata Memorial Centre (TMC), which also includes under its umbrella the Tata Memorial Hospital (TMH), one of the largest cancer hospital in Asia. The Tata Memorial Centre is the national comprehensive cancer centre for the prevention, treatment, education and research in Cancer and is recognized as one of the leading cancer centers in this part of the world. The Tata Memorial Centre is an autonomous grant-in-aid institution of the Department of Atomic Energy (DAE), Government of India, registered under the Societies Registration Act (1860) and the Bombay Public Trust Act (1950). Its Governing Council is headed by the Chairman, Atomic Energy Commission, Government of India. ACTREC is situated in Kharghar, Navi Mumbai and has the mandate to function as a national centre for treatment, research and education in cancer.
ACTREC comprises of 2 arms - one for basic research and another for clinical research. The basic research building was inaugurated in March 2002 at the new site of ACTREC in Kharghar, Navi Mumbai. The clinical research arm of ACTREC comprising of the Clinical Research Centre (CRC) became functional from March 2005. It started as a 32 bedded hospital which has expanded over these years and currently ACTREC has a 123-bed hospital fully equipped with state-of-the-art diagnostic and therapeutic facilities.

The hospital has varied health professionals recruited to ensure smooth function and provide quality patient care. ACTREC has 113 nurses on roll with approximately 50 percent nurses on permanent posts. The researcher selected this hospital as she is familiar with the setting, it was easily accessible especially for observation of practices, the nurses could be contacted whenever required and patients admitted here could benefit from the intervention.

3.5 POPULATION

A population is the entire aggregation of cases in which the researcher is interested. In this study population refers to all nurses working in the cancer hospital in Navi Mumbai.

3.6 SAMPLE

A sample is a subset of the entities that make up the population. In this study sample refers to Staff Nurses working in ACTREC at time of study and fulfilling the inclusion criteria.

3.6.1 SAMPLE SIZE

Sample size is the number of subjects, events, behaviors or situations that are examined in a study. In this study, the sample size of nurses for knowledge was 113 nurses, Practice for hands off was assessed in 102 nurses, Practice for admission
process was assessed for 30 nurses and an audit of SBAR form was undertaken for 20 nurses.

3.6.2 CRITERIA FOR SAMPLE SELECTION

INCLUSION CRITERIA

Inclusion sample criteria are those sampling characteristics that the subjects or elements must possess to be considered part of the target population. Inclusion criteria for assessing knowledge with regard to communication was

- Nurses working in oncology units.
- Nurses who are willing to participate in the study.

Inclusion criteria for assessing practice of handoff and admission process were

- Nurses actively involved in bedside care

3.6.3 SAMPLING TECHNIQUE

A sampling plan or technique outlines strategies used to obtain a sample for the study. The sampling plan may use probability or non-probability sampling methods.

Simple random sampling is the most basic of the probability sampling plans and mostly achieved by selecting samples by use of a computer program. Convenient sampling is a non probability sampling technique that includes subjects who happened to be in the right place at the right time. It is also referred to as accidental sampling.

In this study both probability and non probability sampling technique was used.

Non-probability convenience sampling

1. For knowledge: All nurses working in ACTREC were included in the study.
2. For hands off practice: All nurses involved in direct bedside care were included. All in charges of the units were excluded from the study.
3. For patient satisfaction feedback questionnaire, non-probability convenience sampling was used.

Probability simple random sampling
4. For admission practice: Thirty nurses were selected by simple random sampling method using research randomizer software. Representations of male and female nurses and from all units were considered for sampling.
5. For audit of SBAR form, twenty nurses were selected by random sampling using research randomizer software.

3.7 INSTRUMENT
An instrument (Tool) is the device to collect data.\textsuperscript{6}

The following tools (Instruments) were used to collect data:
1. Self instructional module on communication skills for nurses
2. A structured questionnaire to assess the knowledge
3. A structured observation checklist to assess the practices related to admission process and shift hands off.
4. Situation, Background, Assessment, Recommendation (SBAR) form to capture information of patients.
5. Audit checklist and clinical record to identify compliance to SBAR form.
6. An opinionnaire of nurses regarding the self instructional module
7. Patient feedback and satisfaction questionnaire on nurse’s communication.

3.7.1 DEVELOPMENT OF SELF INSTRUCTIONAL MODULE (Phase I)

The main aim of the module was to enable the nurses to develop personal and professional communication skills and to facilitate the application of those skills in clinical setting. The researcher employed the following steps to complete phase I of the study:
1. Analyze: An extensive review of literature via books, journals, articles was undertaken to identify various components of communication essential for providing effective nursing care in clinical setting. Prior to the development of
the self instructional module, the researcher gathered information from patients, doctors, other healthcare professionals regarding communication of nurses working in ACTREC. The researchers own observations of nurse-patient interaction and nurse-nurse interaction revealed that while the nurses at ACTREC are good, an improvement in their communication would be an added asset. Discussion with various nursing leaders also highlighted the various aspects of communication that require enhancement.

2. Design: Learning objectives were identified based on specific skill and knowledge required by nurses. Evaluation of outcomes to be achieved was also identified for eg. Questionnaire, observation checklist.

3. Develop: The above measures helped the researcher to have clarity and based on the above inputs, the module was developed. Some ideas for illustration were sourced from the internet. An artist drew the illustrations which were mostly cartoons/images. Once the module was ready, it was sent to experts for content validity and to determine if the content was accurate and current. Experts suggested that the contents of the module need to be shortened and better organized. Suggestions and corrections were incorporated. The content was organized under the guidance of the guide and the final version on ‘Clinical Communication Skill for Nurses – a training module was ready.

The self instructional module had six sections

Section I  - About communication
Section II - Types and modes of communication
Section III - Barriers to communication.
Section IV - Skills that facilitate communication
Section V - Communication between nurses: Hands off using SBAR
Section VI - Documentation

4. Preliminary testing: the module was distributed to six nurses to identify the suitability of content, difficulty in language, feasibility and practicality. They reported that the content was simple and easy to understand and the illustrations were self explanatory. The module was again tested during pilot study.

5. Evaluation: A summative evaluation to measure the learning outcomes after implementation of self instructional module was planned to test knowledge
and change in practice and thus establish the efficacy of the self instructional module.

3.7.2 STRUCTURED QUESTIONNAIRE

This tool was prepared to identify the nurse’s knowledge in relation to selected aspects of communication. The nurses are to respond to closed ended questions with response alternatives designated by researcher. The tool had two sections:

1. Section one consisted of items to assess the demographic data such as age, gender, qualification and experience.
2. Section two consists of 40 items. There were twenty five multiple choices questions having four options with one correct answer and fifteen true or false questions.

Questions based on the module and related to various aspects of communication e.g. Verbal, non verbal, barriers, communication skills and documentation were incorporated to cover all aspects. Total score for questionnaire was forty. Each correct response would get a score of one. (Appendix G, H, I)

3.7.3 STRUCTURED OBSERVATION CHECKLISTS (Phase II)

The creativity of structured observation lies not in the observation itself but, rather, in the formation of a system for accurately categorizing, recording and encoding the observations and sampling the phenomena of interest. An observation checklist comprising of twenty two items for handoff (nurse – nurse) and an observation check list comprising of fifteen items for admission process (nurse to patient) were developed. The handoff was divided into two domains namely verbal communication (13 items) and nursing responsibility (9 items). The admission process was further grouped into domains e.g. Verbal (6 items), non-verbal (3 items), communication skill (3 items) and documentation (3 items). The contents were as per standards of nursing practice and incorporated information pertaining to communication during shift hands off and during admission process. (Appendix K, L)
3.7.4 SITUATION BACKGROUND ASSESSMENT AND RECOMMENDATION (SBAR) FORM

SBAR is an acronym for **Situation, Background, Assessment, and Recommendation**. The SBAR tool was developed by Kaiser Permanente. It is a technique used for prompt and appropriate communication in health organizations. This communication model has gained popularity in healthcare settings, especially amongst professions such as nursing. It is a way for healthcare professionals to communicate effectively with one another, and also allows for important information to be transferred accurately. The format of SBAR allows for short, organized and predictable flow of information between professionals. SBAR has been suggested as a means to overcome communication problem by applying a system and structure to the presentation of information.

The format by Kaiser Permanente was modified by researcher to suit the hands off requirement. This form contained all information pertaining to individual patients, was to be used during shift hands off between nurses. (Appendix R)

3.7.5 AUDIT CHECKLIST

An audit checklist with twenty nine points covering all aspects of SBAR form was prepared by researcher to verify if all pertinent information related to patient was documented. Apart from the checklist, the researcher would countercheck the documentation with patient’s clinical records.

3.7.6 A SEMI STRUCTURED OPINIONNAIRE

Semi structured Opinionnaire was used to find out the opinion of nurses regarding the self instructional module. It had five open ended questions regarding the module, two statements on their level of confidence about use of SBAR for patient safety, one question on areas they require improvement and suggestions if any about the module. (Appendix J)
3.7.7 STRUCTURED FEEDBACK AND SATISFACTION QUESTIONNAIRE ON NURSE’S COMMUNICATION

A structured questionnaire having 10 statements using three point Likert scale was used to elicit response from patients about nurse’s communication with them and one statement using a five point Likert scale was used to elicit information about their level of satisfaction with nurses’ communication. (Appendix M)

3.8 TECHNIQUE OF DATA COLLECTION

Technique is the means or procedure for doing something\(^\text{10}\) The following techniques were used in this study

- a) Self report method / Interview schedule for questionnaire on knowledge and opinionnaire for nurses and patient feedback and satisfaction on nurses communication.
- b) Non participatory direct observation for hands off and admission process
- c) Retrospective audit for SBAR form documentation

Self report is a method of collecting data that involves a direct report of information by the person who is being studied.\(^\text{6}\) The researcher used this technique for data collection as the nurses were literate and would be more comfortable responding to the questionnaire on their own. This technique was also used for patients to elicit their feedback on nurse’s communication. Interview technique was used for patients who were illiterate. A non participatory direct observation technique was used to observe the practice of nurses in relation to selected aspects of communication of nurses in their interaction with patients during admission process and with nurses during shift hands off. Retrospective means relating to the past or something that happened in the past and audit means a methodological examination and review.\(^\text{10}\) In this study retrospective audit refers to methodological review of the SBAR form with patients’ clinical record already documented in past few days.
3.9 VALIDITY

Validity is the degree to which an instrument measures what it is supposed to measure.\(^6\) Validity of an instrument is a determination of how well the instrument reflects the abstract concept being examined.\(^5\) Content validity concerns the degree to which an instrument has an appropriate sample of items for the construct being measured. An instrument's content validity is based on judgment.\(^6\) Validity of the structured questionnaire, observation checklist, opinionnaire, patient feedback and self instructional module feedback form and self instructional module was established by giving it to nine nursing experts, one clinician, one language expert and one communication expert. Content validity ratio (CVR) was calculated using the formula CVR = \([E-(N-2)] / (N/2)\). CVR can measure between -1.0 and 1.0. The closer to 1.0 the CVR is, the more essential the object is considered to be\(^11\). The CVR was in range from 0.33 to 1 (Appendix O). Thus the content validity of the tool (instrument) was established. In content validity, most of the experts agreed on the contents selected for the booklet and instrument for the study. There were few items which were repeated or not relevant which was deleted from the study. Format for handover was organized sequentially. Suggestions/corrections were incorporated wherever required. After establishing content validity, Patient feedback and satisfaction questionnaire was translated from English to Hindi and Marathi by two experts. (Appendix F, O)

3.10 RELIABILITY

The reliability of a quantitative instrument is a major criterion for assessing its quality and adequacy. An instrument’s reliability is the consistency with which it measures the target attribute.\(^6\)

Questionnaire: Reliability of the knowledge questionnaire was established by test retest and analyzed using Cronbach Alpha as a measure of agreement.

Formula:\(^{12}\)

\[
\frac{k}{k-1} \left(1 - \frac{\sum_{j=1}^{k} \text{var}(x_j)}{\text{var}(x_0)}\right)
\]
where \( \text{var}(x_0) \) is the variance of the observed total test scores, and
\[
\sum_{i=1}^{k} \text{var}(x_i)
\]
the variance of component \( i \) for the current sample of persons.

Internal consistency index for questionnaire was 0.74

Observation: An inter rater reliability analysis using the Kappa statistic was performed to determine consistency among raters.

Formula\(^{12}\):
\[
\kappa = \frac{\Pr(a) - \Pr(e)}{1 - \Pr(e)}
\]
where \( \Pr(a) \) is the relative observed agreement among raters, and
\( \Pr(e) \) is the hypothetical probability of chance agreement,

Admission process: “The inter rater reliability for the raters was found to be Kappa = 1.00 (p <.0.001) and
For handoff: Kappa = 0.83 (p <.0.001).

3.11 ETHICAL CONSIDERATION

This study has been approved and waver of consent was granted by the Institutional Ethics Committee of Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Tata Memorial Centre, Kharghar, Navi Mumbai, India (Appendix B)

3.12 PILOT STUDY

A pilot study is a smaller version of a proposed study conducted to develop and refine the methodology, such as the treatment, instruments or data collection process to be used in the larger study.\(^{5}\) The pilot study was conducted from December 2013 to January 2014 at Tata Memorial Hospital, Parel, in order to test the feasibility of the tool and the technique. Ten nurses, who fulfilled the inclusion criteria, were identified based on non probability convenient sampling. The nurses were informed about the purpose and procedure of the study. A pre test was undertaken followed by
one observation of practice. The self instructional module was distributed to the participants along with information that a post test will be conducted after seven days. The post test along with post observation was carried out after 10 days using the same questionnaire.

During the pilot study, the researcher realized that observation requires more time as the nurses were not available as per the plan. Observation of each hand off took 15-20 minutes and the admission process was unpredictable e.g. late night admissions, no admission on certain days and nurses’ unavailability suggested the need for adequate time planning and need for assistance in data collection. The participants also reported that they require more than a week to read through the module. A decision was taken to complete the pre test observation followed by testing of knowledge and distribution of self instructional module based on pilot study findings.

### 3.13 Data Collection Process

The phenomena in which the researcher is interested must be translated into data that can be analyzed.\(^6\) Data collection commenced from March 10, 2014 to September 19, 2014 after Institutional Review Board gave its approval. The nature and purpose of the study was explained to all nurses.

One research assistant was selected to assist with observation of practices of shift hands off and admission. The research assistant was an employee of the institute and had completed Masters in nursing and was also familiar with the basics of research methodology and expressed willingness for the same. Training on the objectives of the study, purpose of the tool and method for scoring the checklist was undertaken by researcher. Individually each item in the tool was reviewed, to help gain clarity. The research assistant had to document the observations by placing a yes (Y) or no (N) and not applicable (NA) if the item was not relevant at that specific time. Before initiating the actual data collection an inter rater reliability was carried out to identify if the observations were consistent. (Appendix N, Q)
Phase I

Pre test observation of nurses for hands off and admission process.

Research observation involves a systematic selection, observation and recording of events relevant to problem under study. In this study a structured observational checklist was used to collect data for shift hands off and admission process. Numbers were assigned to all nurses by the statistician as per random tables using graph pad quickcalc software.

Five conveniently selected nurses were observed daily during shift hands off. Admission process was initiated for 30 nurses using simple random sampling. The nurses were observed by the researcher and research assistant during the procedure of shift hands off and admission process. The observation was carried out in the clinical area. In the selected institute the hands off timings were from 7 am to 7.30 am for incoming morning shift and from 1.30 to 2.30 pm for the incoming evening shift. Each hands off observation was completed within ten minutes. For admission process since the admission time was not defined, each of these observations was carried out as and when it occurred. Each observation for admission process was completed within 20 minutes. Three observations of hands off were undertaken for each nurse with a gap of seven days between two observations. At the end of phase I, practices in relation to hands off were assessed from 102 nurses and practices in relation to admission process were assessed from 29 nurses.

Phase II

Pre test of knowledge and distribution of self instructional module.

Self report is the most widely used data collection method. This data can be gathered either orally in an interview or in writing in a written questionnaire. In this study self report method of data collection was used. Written questionnaire was administered by the researcher. The auditorium with seating capacity of 80 was booked for the same from 1.30 pm to 4 pm. This timing was selected as this was an overlap time and both morning and evening shift nurses would be available. Their consent to partake in the study was solicited and they were also assured of anonymity and confidentiality by assuring them that a random number generated through a computerized random table will be assigned by the statistician. The nurses were
informed about the objective of the study and were instructed to attempt all questions, place a circle on the correct answer and in case they want to change their response, they were to cross out the wrong response and place a circle on correct response. Each participant was given one hour to complete the questionnaire. The statistician assigned a code as per the random number table to each individual once they completed the questionnaire. After completion of the questionnaire, the self instructional module on “Clinical communication skill for nurse: a training module was handed to the nurses. They were instructed to read the module and a time period of 4 weeks were given. To facilitate reading, the auditorium was kept open from 1 pm to 4 pm daily.

Phase III

Post test of knowledge, completion of opinionnaire and post test observation, audit of SBAR and patient feedback.

A post test was carried out at the end of four weeks. They were also requested to complete the opinionnaire about their views on the training module. This was followed by post test observation of the shift hands off and admission process. Each nurse was observed three times with a gap of 7 days for shift hands off. The admission process was also observed thrice as and when the patient was admitted.

An audit involves an independent scrutiny of qualitative data and relevant supporting documents by the external reviewer to determine the dependability and conformability of qualitative data. Retrospective audit of SBAR form was undertaken to identify correct use of the form and if relevant information was documented in the SBAR.

Records of twenty nurses, selected by random sampling were audited. The clinical record of patient was crosschecked with the form. The data if correctly documented was recorded as ‘Yes’ and if not documented was recorded as ‘No’. Two formats of each selected nurse were audited two times.

A patient feedback form was given to the patients/parents of children admitted in the institution. The feedback form was translated into two languages i.e. Hindi and Marathi. They were informed about the purpose of the feedback. An interview was
carried out for patients who were illiterate in a language they understood. Their responses were recorded by the researcher/research assistant. Thus the efficacy of Self Instructional Module was established.

3.14 PLANS FOR DATA ANALYSIS

1. To assess the knowledge regarding clinical communication among nurses working in an oncology hospital before and after providing the self instructional module.
   **Descriptive statistics and Paired t test**
2. To assess the practices of nursing staff in relation to clinical communication skills before and after providing the module
   **Descriptive statistics, Paired t test and Wilcoxon signed rank test**
3. To compare the knowledge and practices of nursing staff before and after providing instructional module.
   **Karl Pearson's formula for co-relation of coefficient**
4. To find out the association between clinical communication skills and selected variables such as age, gender, work experience, professional education.
   **Paired t test and Wilcoxon signed rank test**
5. To find out the opinion of nursing staff regarding the self instructional module.
   **Descriptive statistics and qualitative analysis**
6. To assess the patient satisfaction regarding communication received from nurses.
   **Descriptive statistics**

3.15 SUMMARY

This chapter dealt with research approach, design, variables under study, setting, population, sample, sample size, inclusion criteria, instrument, technique, validity and reliability, pilot study, data gathering process and plan for data analysis.
3.16 REFERENCES

10. Webster M. Merriam-Webster online dictionary. 2006.