

**A STUDY TO ASSESS THE EFFECTIVENESS OF STRUCTURED
TEACHING PROGRAM FOR NURSES ADMINISTERING
INTRAVENOUS CHEMOTHERAPY, IN PSG HOSPITAL,
COIMBATORE**



By

PRAVEENA ARUL

A dissertation submitted to **The Tamil Nadu Dr. M G R Medical University,**
Chennai, in partial fulfillment of requirement of the degree of

Master of Science in Nursing
Branch I Medical Surgical Nursing

2016

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CERTIFICATE

Certified that **“A STUDY TO ASSESS THE EFFECTIVENESS OF STRUCTURED TEACHING PROGRAM FOR NURSES ADMINISTERING INTRAVENOUS CHEMOTHERAPY”** is the bonafide work of **PRAVEENA ARUL**, PSG College of Nursing, Coimbatore, submitted in partial fulfillment of requirement for the degree of Master of Sciences in Nursing to **The Tamil Nadu Dr. M G R Medical University, Chennai.**

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ABSTRACT

A study to assess the effectiveness of structured teaching program for nurses administering intravenous chemotherapy, in PSG Hospital, Coimbatore

Occupational exposure to cytotoxic substances continues to be a hazard in the healthcare setting. “It is therefore highly important for oncology nurses to apply proper drug handling techniques and procedures with great care to prevent such exposure”

Objective of the Study:

1. Evaluate the effectiveness of the structured teaching program for the nurses administering intravenous chemotherapy.

Research Methodology:

The study was conducted in PSG Hospitals, Coimbatore and the research method adopted was Quasi experimental one group Pre-test and Post-test design. As per the inclusion criteria, 32 samples were selected. The pre-test score of knowledge and skill level was assessed by a structured questionnaire and checklist respectively. A structured teaching program on intravenous chemotherapy (duration of 30-45 minutes) was given and the post-test assessment was done on the 7 day by using the same tool.

Major Findings of the Study:

The study finding displayed an increase in the knowledge level and skill level following the structuring teaching program. In this study, the statistical analysis showed that there was an association ($p < 0.05$, $\chi^2 = 5.991$) between previous knowledge on intravenous administration of chemotherapy and educational status. There was positive correlation seen between pre and post-test level of knowledge and skill among nurses.

Conclusion:

This study finding showed that structured teaching program was helpful in improving knowledge and skill among nurses administering intravenous chemotherapy.

Key words:

Effectiveness, Structured teaching program, Intravenous, Chemotherapy.

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CHAPTER I

INTRODUCTION

1.1 Background of the study:

Non-maleficence, which is derived from the Latin phrase “Primum non nocere” means "first, do no harm, is one of the principal precepts of bioethics that all healthcare professionals are expected to adhere to. It also means, "given an existing problem, it may be better not to do something, or even to do nothing, than to risk causing more harm than good." This reminds the health care provider that they must consider the possible harm that any intervention might do. It is invoked when debating the use of an intervention that carries an obvious risk of harm but a less certain chance of benefit.

Cancer is the second leading causes of fatality among adults worldwide. In India, the International Agency for Research on Cancer has indirectly estimated that about 635,000 people have died from cancer in 2008, representing about 8% of all estimated global fatalities from cancer and about 6% of all deaths in India. Cancer prevalence in India is estimated to be around 2.5 million, with over 800,000 new cases observed each year. The absolute number of cancer fatalities in India has been projected to increase because of population growth, urbanization, industrialization, and lifestyle changes. World Health Organization (WHO) has estimated that the number of cancer fatalities in India is projected to increase 700,000 by 2015. **(National institute of occupational safety and hazards)**

The global morbidity and mortality rate of cancer shows approximately 14 million new cases and 8.2 million cancer related deaths in 2012. The number of new cases observed is expected to rise by about 70% over the next 2 decades. Among men the 5 most common sites of cancer, diagnosed in 2012 were lung, prostate, colorectum, stomach, and liver cancer. Among women the 5 most common sites diagnosed were breast, colorectum, lung, cervix, and stomach cancer. Tobacco usage is the most important risk factor for cancer, causing around 20% of global cancer fatalities and around 70% of reported lung cancer cases globally. **(World Health Organization)**

The treatments for cancer are chosen depending on the type, location, and grade of the cancer as well as the person's health and wishes. The treatment intent may be curative or not curative. The treatment options for cancer includes chemotherapy among other such treatments.

Chemotherapy is the use of cytotoxic drugs in the treatment of cancer. It is one of the four treatment modalities (the other being surgery, radiation therapy, and biotherapy) that provide cure, control, or palliation. **(Martha E. Langhorne et al., 2007)**

Chemotherapy may be used to achieve control over the disease by preventing or slowing down the growth of a malignant tumor and thus prolonging survival and it may be used palliatively in the management of symptoms such as pain or breathlessness. **(Jessica Corner et al., 2008)**

The primary aim of chemotherapy is to have a systemic effect on cancer cells and therefore prevent cell replication and halt cell division. Consequently healthy cells as well as malignant cells will be affected hence the patients can anticipate certain side effects of their treatment in areas of high cell division, such as bone marrow depression, gastrointestinal disturbance and alopecia. These side effects are usually reversible depending on the drug type and total dose given as well as the patients existing health. Chemotherapy can be used in a number of ways and also in conjunction with other anticancer treatments. It can be used prior to surgery to reduce the size of a tumor and therefore minimize the amount of surgical intervention required. **(Nora Kearney et al., 2006)**

Chemotherapy administration is primarily the responsibility of a registered nurse who has specific knowledge about the pharmacology and dosing of the drug as well as competence in preparation, administration and management of toxicity. Chemotherapeutic drugs are associated with serious side effects, including carcinogenicity and teratogenicity. Health care workers who handle antineoplastic drugs can be exposed to low doses of the drug by direct contact, inhalation and injection and could be at risk for some of the same side effects associated with the therapy. It is

essential that any health care provider working with cytotoxic drugs follow the occupational safety and health administration guidelines to prevent injury to self and others. **(Phipps, 2007)**

Occupational illness normally develops over a period of time because of workplace conditions. Such conditions might include exposure to disease causing bacteria and viruses, chemicals or dust. Under the Occupational Health and Safety Act, occupational illness is defined as a condition that results from exposure in a workplace to a physical, chemical or biological agent to the extent that the normal physiological mechanisms are affected and the health of the worker is impaired.

Occupational exposure from hazardous drugs may pose a significant risk to healthcare workers. Since the mid-1980s, several organizations have published recommended hazardous drug handling guidelines. Most recently, the National Institute of Safety and Health (NIOSH) published an alert that presents the most updated recommendations for hazardous drug handling. Implementing these recommendations may prevent or reduce the inadvertent exposure to these drugs, thus minimizing the potential adverse health effects associated with their handling. **(Susan Martin 2005)**

Therefore, virtually all cancer chemotherapy is a delicate compromise between effectiveness and toxicity, resulting in significant side effects. Patients and physicians accept this because the alternatives are limited and the progression of often fatal disease usually occurs more quickly without some intervening form of chemotherapy treatment.

1.2 Need for the study

Drugs have a successful history in treating illnesses, and they are responsible for many of our medical advances. However, virtually all drugs have side effects associated with their use by patients, and both patients and nurses who handle them are at risk of suffering these effects that might result from exposure to even very small concentrations of certain hazardous drugs. Many antineoplastic drugs are known to be carcinogenic, teratogenic and mutagenic to humans. There is a potential occupational exposure risk to cytotoxic drugs. Nurses are among the main groups of professionals that are exposed to these drugs in patient care settings. Although the potential therapeutic benefits of

hazardous drugs outweigh the risks of side effects for ill patients, exposed nurses risk these same side effects with no therapeutic benefit. Most drugs are given to the patient through an intravenous (IV) drip, but some drugs are “pushed” via a syringe. In either case, drug administration poses a risk to the nurses from a spill or release from the IV bag or through a pressured release during the drug “push”. Drug administration to patients requires wearing personal protective equipment as used by pharmacists in the event of a spill or other unplanned release. **(American cancer society)**

“Occupational exposure to anticancer drugs have been shown to be associated with both increased incidence of malignancy in male and female healthcare workers, as well as fetal developmental effects in their offspring”. Occupational exposure to cytotoxic substances continues to be a hazard in the healthcare setting. “It is therefore highly important for oncology nurses to apply proper drug handling techniques and procedures with great care to prevent such exposure”. **(Oncology nursing society)**

It is very important to know the specific guidelines for administration of chemotherapeutic drugs. In addition to understanding that, drugs may pose an occupational hazard to health care professionals who do not follow safe handling guidelines. **(Lewis et al., 2012)**

The health care member who handles the patients should wear gloves and disposable gowns when handling body secretions of patients who have received chemotherapy within the previous 48 hours. **(Joyce M. Black, 2009)**

Protection of health care workers (HCWs) who are exposed to cytotoxic drugs is a global concern. Working in a chemotherapy unit increases the exposure of health care workers, especially nurses, to numerous hazardous materials if they do not protect themselves according to standard guidelines. Occupational exposure may occur directly through preparation, administration and handling of drugs or indirectly through contact with contaminated surfaces and patients' secretions (e.g., urine, vomitus, etc). Absorption of a cytotoxic drug may occur via the skin, mucous membrane or through the inhalation of drug particles. The exposed health care workers may suffer from nausea, vomiting, headache, vertigo, hair loss, abdominal pain, and skin and allergic

reactions. Pregnant staffs run the risk of developing more serious complications including abortion, congenital anomalies and premature births. Carcinogenicity is the most serious side effect of cytotoxic drugs that would affect health care workers after long-term exposure to them even at miniscule doses.

Over the past decades, several standards, regulations and guidelines have been proposed to control occupational exposure to cytotoxic drugs those cover all aspects including administrative control, engineering control and personal protective equipment. So far, few studies have been conducted about the complications of exposure to antineoplastic drugs and the health care workers' compliance with national and international guidelines. To the best of our knowledge, little is known about the staff's safety and their compliance with the standard regulations. **(Christopher R Friese,etal., 2011)**

Unintentional chemotherapy exposure can affect the nervous system, impair the reproductive system and bring an increased risk of developing blood cancers in the future. These exposures are as dangerous to a nurse's health as being accidentally stuck with a needle. "Now a days needle stick incidents have minimized so they are rare events that elicit a robust response from administrators. Nurses go immediately for evaluation and prophylactic treatment if this happens. But we don't have that with chemotherapy exposure". **(Live science, 2011)**

Nurses must be aware of the safe handling of chemotherapeutic drugs, which include assessment of drug preparation, administration, and disposal. "It is clear that nurses remain at risk of exposure. Many don't have adequate knowledge about the effects because they are not aware of the literature, while others may be aware of the problem and are either very concerned about it, or they believe that their workplace is safe".

Therefore, the occupational safety requirements in the management of cancer has motivated the researcher to conduct a study to determine the effectiveness of nurses administering chemotherapy through intravenous administration by providing them sufficient knowledge in the practice of chemotherapy, thereby helping them protect

themselves as well as the patients undergoing the treatment, from the harmful exposures, to create a safe working environment and to empower them to manage any complications.

1.3 Statement of the problem:

A study to assess the effectiveness of structured teaching program for nurses administering intravenous chemotherapy, in PSG Hospital, Coimbatore.

1.4 Objectives:

- Assess the existing knowledge of the nurses administering intravenous chemotherapy.
- Assess the skills of the nurses administering intravenous chemotherapy.
- Evaluate the effectiveness of the structured teaching program for the nurses administering intravenous chemotherapy.
- Determine an association between pre-test evaluation of nurse's knowledge and skill regarding administration of intravenous chemotherapy and their selected demographic variables.
- Find relationship between pre and post-test knowledge and skills of the nurses about intravenous administration of chemotherapy.

1.5 Assumptions:

1.5.1 Nurses administering chemotherapy may not have undergone special training.

1.5.2 Nurses with special training in intravenous chemotherapy will take adequate protective measures for self and patients while administering intravenous chemotherapy.

1.6 Hypothesis:

H₁: There will be a significant improvement in the level of knowledge of the nurses administering intravenous chemotherapy before and after the implementation of the structured teaching program.

H₂: There will be a significant improvement in the skills of the nurses administering intravenous chemotherapy after the implementation of the structured teaching program.

H₃: There will be a significant association between pre-test knowledge and skills of the nurses with their selected demographic variables.

H₄: There will be a significant relationship between knowledge and skills of the nurses on intravenous administration of chemotherapy in pre and post-test.

1.7 Delimitation:

- The study population was delimited to the chemotherapy administering nurses who are working in selected wards.

1.8 Operational definitions:

- **Effectiveness:** Refers to the increase in knowledge and skill regarding intravenous chemotherapy among nurses (administration and its hazardous) after the implementation of the structured teaching program which is measured by structured questions on knowledge, administration, preparation, safe handling, side effects of chemotherapy and its management and checklist regarding preparation and administration.
- **Structured teaching program:** Refers to the programme developed by the researcher to educate on administration, hazards and precaution of intravenous chemotherapy to nurses with the help of computer aided tools for about 30-45mts.
- **Chemotherapy:** In this study, it refers to the administration of intravenous drugs as prescribed for treating cancer.
- **Intravenous:** In this study, the term intravenous refers to the administration of the prescribed drug through a selected vein.

1.9 Projected outcome:

Structured teaching program could help to improve the knowledge and skills of the nurses administering intravenous chemotherapy.

1.10 Conceptual frame work:

The conceptual framework for this study was derived from general system model (Ludwig Von Bertalanffy, 1968). It is regarded as a universal grand theory because of its unique relevancy and applicability. It is composed of both structural and functional components that interact within a boundary that filters the type and rate of exchange with the environment. Living system terms are open because there is an ongoing exchange of matter, energy, and information. Through the process of selecting the system which regulates the type and the amount of input through self-regulation to maintain the system equilibrium or homeostasis. Some types of input are used immediately in their original state where as the other complex transformations are continuously processed through the system and released as output. The following components in the modified general system model are as follows:

Input: Input is the information needed by the system. It includes demographic variables and knowledge and skills were evaluated based upon pre-test structured questionnaires regarding knowledge, drugs, safe handling, administration, complication and its management about chemotherapy and check list on preparation and administration of intravenous chemotherapy.

Through put: Through put is the activity phase. It is a process that allows input to change. It includes the provision of a structured teaching program with the help of computer aided tools for the nurses who are administering intravenous chemotherapy.

Output: The information are continuously processed through the system and released as output in an altered state. It includes evaluation of the nurse's knowledge and skill on administration of intravenous chemotherapy with the same structured questionnaires and checklist to bring changes in the level of knowledge and skills of the nurses.

Feedback: It is the response of the environment to the system. Feedback may be positive or negative or neutral. It is necessary to strengthen the input and throughput and modify them as desired when the results show any inadequate practice of intravenous administration of chemotherapy.

Summary

This chapter deals with the introduction, need for the study, statement of the problem, objectives, assumption, hypothesis, operational definitions, projected outcome, and conceptual framework.

CHAPTER-II

REVIEW OF LITERATURE

A literature review is a description and analysis of the literature relevant to a particular field or topic. It gives an overview of what has been said, who the key writers are, what are the prevailing theories and hypotheses, what questions are being asked and what methodologies are appropriate and useful.

A literature review uses as its database, reports of primary or original scholarship and does not report new primary scholarship itself. The primary reports used in the literature may be verbal, but in the vast majority of cases, reports are written documents. The type of scholarship may be empirical, theoretical, critical or methodological in nature. Second a literature review seeks to describe, summarize, evaluate, clarify and integrate the content of primary reports. **(H.M. Cooper, 1988)**

This chapter consists of literature and research studies related to;

- 2.1 Knowledge on chemotherapy
- 2.2 Administration of chemotherapy
- 2.3 Safe handling of chemotherapy
- 2.4 Side effects and managements of chemotherapy

2.1 Knowledge on chemotherapy

A randomized controlled trial study was conducted to assess impact on patient distress, treatment-related concerns, the prevalence and severity of chemotherapy effects among 192 cancer patients at the Peter McCollum cancer center in Melbourne, Australia. Education was given to patients by DVD (digital video disc). The study result shows that there is no significant decrease in patient distress but there is decrease in psychological status of the patient to cope with their situation ($p=0.027$) and prevalence and severity of chemotherapy effects ($p=0.001$). It concludes that focus is required on more diverse patient populations to ensure generalizability. **(S.Aranda, et al., 2009)**

A cross sectional descriptive study was conducted to determine the nurses' knowledge and education about oral care in cancer patient undergoing chemotherapy and radiation therapy among 158 staff nurses working in oncology related areas from four different hospitals in Dakshina Kannada district and Udupi district of Karnataka state, India. Semi structured questionnaires were used throughout the study, the result shows that majority 81 (51.3%) of the staff nurses had poor knowledge of oral care on cancer patients whereas 87 (55.1%) reported that knowledge acquired through basic education on oral care is not sufficient. Most of the staff nurses 115 (72.8%) had not received basic education on oral care of cancer patients. There was significant association between knowledge and variables such as designation (.005), years of work experience (.040) and years of experience with cancer patients (.000) at 0.05 levels. The finding shows that the lack of knowledge suggest the need to develop and implement continuing nursing education programs on oral care specifically for patients receiving cancer treatments, for improving the knowledge of staff nurses in order to render comprehensive care to the patients. **(Radhika R Pai, et al., 2013)**

A descriptive cross-sectional study was conducted for determining the knowledge and practice on oral care among the patients receiving chemotherapy a total of 102 respondents, visiting B.P. Koirala Memorial Cancer Hospital, Bharatpur Chitwan. A structured and semi-structured interview schedule consisting of questions related demographic characteristics, knowledge and practice were used. The study result shows that the knowledge on oral care was adequate among 23.4% of the respondents and 18.6% of the respondents had adequate practice receiving chemotherapy. Only 28.4% respondents had adequate knowledge, among total respondents 60.7% of the respondents had adequate knowledge on the prevention of oral problems and 55.8% of the respondents had adequate knowledge on treatment of oral problems. Nurses were found as a main source of information on oral care. Thus the study also concluded that adequate knowledge on oral care should be provided to the patients before undergoing chemotherapy. **(Acharya Radha et al., 2013)**

A quasi-experimental research design study was conducted to develop nursing care standards for cancer patients undergoing chemotherapy in oncology unit and outpatient clinic of oncology at Assiut university hospitals, Egypt. Fifty four samples were used for the study. Tool utilized for data collection were Health team opinionative sheet, Nurses knowledge standards level test for cancer patient undergoing chemotherapy, and Nurses performance observation standards level checklist for cancer patient undergoing chemotherapy. The results show that the pre standards application 53.3% of study group were poor in knowledge, on immediate standards application 100% of study group were good in knowledge, after 1 month of standards application 80% of study group were good in knowledge, and after 3 months 60% of study group were satisfied in knowledge, and regarding to nurse's performance the study conclude that the level of performance improved in all procedures immediately after one month and after three months than pre-standards application. **(Asa Al Magid et al., 2012)**

A cross-sectional, exploratory study was conducted in two hospital-based outpatient chemotherapy clinics in Baltimore, to explore oncology nurses' practice behaviors and knowledge of chemotherapy-induced peripheral neuropathy (CIPN) in the assessment of patients with cancer. Total sample of 39 oncology nurses were selected. Structured questionnaire was used as a tool for this study. The result shows that all respondents indicated CIPN assessment is essential in their oncology role, but 75% rated their CIPN assessment skills as fair to poor. Assessment practices did not routinely include neurologic physical assessment. In addition, 82% believed CIPN is a significant problem for patients. The study concludes that the indicated participants had knowledge deficits pertaining to CIPN and lacked training, proficiency, and confidence in neurologic physical assessment. Education and training programs are needed to improve knowledge and neurologic assessment skills. **(Madelaine Binner et al., 2011)**

A cross-sectional study was conducted to assess the effectiveness of knowledge regarding breast cancer and chemotherapy among 239 health science students from local public university in Terengganu, Malaysia. Data collected based

upon breast cancer and chemotherapy questionnaires (BCCQ). The result shows that majority of students (71.1%) possessed a moderate level of knowledge related to breast cancer and chemotherapy in that 33.1% were unaware of different modes for chemotherapy administration. This study has generally ascertained that knowledge related to breast cancer and chemotherapy among this sample population remains moderate and is not uniformly disseminated. An increase in knowledge is required to ensure an optimal level of knowledge particularly for the junior students and those from courses other than nursing. **(Lua Pei Lin, et al., 2012)**

2.2 Administration of chemotherapy

The qualitative study was conducted to assess knowledge, skill and attitude of oncology nurses in chemotherapy administration at two oncology units of tertiary Hospital Rawalpindi. A single group pre and post-test study design was used on 35 nurses by using verity's tools such as knowledge assessment tool, attitude scale and observation checklist for skill (about 1-1:30 hours). The mean scores of knowledge were calculated by Cochran's Q test showed that knowledge scores have significantly increased with "educational training" (p value < 0.001). The difference in the attitude of the nurses was not found to be statistically significant. The results show that the educational session was found to be effective in improving the knowledge of nurses, however there was no significant change in their attitudes. Hence the study concludes that knowledge is the weakest component and attitude is strongest component of oncology nurses competencies in chemotherapy administration. **(Najma Khan, et al., 2012)**

A cross sectional study was conducted at Ambulatory Oncology Department of Tanta Cancer Institute affiliated to Ministry of Health, Gharbia Governorate. Pre and post-test design were used. Sample included all available (44) nurses and (50) ambulatory oncology patients. The collection of data was achieved by ambulatory oncology nursing checklist, knowledge test, patient education need assessment sheet and development of an education program about ambulatory oncology nursing knowledge and practice activities for dealing with oncology patients undergoing chemotherapy. The study results revealed that a statistical significant improvement

found for the knowledge and practice of studied nurses immediate after three months post program than pre-program. The study finding shows that it is important to conduct in-service training program for ambulatory oncology nurses for dealing with oncology patient undergoing chemotherapy, periodical evaluation and making feedback and enforcement of knowledge and practice. **(Maha Eid, Shokier et al., 2012)**

A randomized controlled trial study design was conducted among 164 patients with a diagnosis of colorectal and breast cancer from cancer hospital in United Kingdom during 24 month period to assess the effectiveness of a symptom-focused home care program in patients with cancer who were receiving oral chemotherapy in relation to toxicity levels, anxiety, depression, quality of life, and service utilization. The duration of follow up was 4.5 months. Toxicity assessment were carried out weekly for the duration of the patients' participation in the trial, and validated self-report tools were used to assess anxiety, depression, and quality of life. Significant improvements were observed in the home care group in relation to the symptoms(.05).The study concludes that a symptom focused home care program was able to assist patients to manage their treatment adverse effects more effectively than standard care. It is imperative that patients receiving oral chemotherapy are supported with such kind of programs, particularly during initial treatment cycles and to improve their treatment and symptom experiences. **(Alex Molassiotis, et al., 2009)**

A multi-method study was conducted to examine the nurse's knowledge and performance on chemotherapy administration among 526 trained nurses across the five London Cancer Networks.The study consists of two component one was to investigate nurse's perspectives of administering chemotherapy to patients with cancer and second one is to develop an understanding, in context, of the work of nurses administering chemotherapy in an outpatient clinic. The results show that overall nurses appear to have a positive attitude towards chemotherapy by realizing that chemotherapy is a more involved process than just administering intravenous drugs and have an awareness of the safety issues and consequences of administration. It concludes the evidence that nurses must have formal education and support in clinical

practice before taking on this role. Experience in this process has positively influenced not only nurse's attitudes towards chemotherapy but also their interactions with patients and colleagues. **(Dr. Theresa Wiseman, et al., 2005)**

A descriptive study was conducted in the Ogun State University Teaching Hospital, Nigeria for identifying the potential sources of stress in cancer care for oncology nurses. A sample of 128 oncology nurses was selected. A structured questionnaire that consisted of two sections (demographic data and questions constructed based on the Medication Administration Error (MAE)). The findings showed that majority of the nurses (89.8%) have made at least one MAE in the course of their professional practice. Fear (mean = 3.63) and managerial response (mean = 2.87) were the two major barriers to MAE reporting perceived among oncology nurses. The study concludes that nurse managers and health care administrators should create a favorable atmosphere that does not only prevent medication errors but also supports nurses' voluntary reporting of MAEs. Education, information and communication strategies should also be put in place to train nurses on the need to report if possible to prevent all medication errors. **(Chinomso, et al., 2014)**

2.3 Safe handling of chemotherapy

An analytic cross sectional study was carried out to evaluate the knowledge of nurse regarding the way of exposure of Cytotoxic Drugs and their safe handling at B.P.Koirala Institute of Health Sciences, Dharan, Nepal. The study was carried among 125 Nurses by using structured and semi structured questionnaires. The study result shows that more than 92% of participants reported usually wear gloves during chemotherapy handling, 6% reported using laboratory coats as protective garments. Usual use of face and respiratory protection was less than 5%. Chemotherapy was reported to be prepared in nursing station where there are no laminar airflow hoods in 100% of work settings. None of the subjects have reportedly provided any type of medical monitoring. The study concludes that Nurses are the main groups exposed to these drugs in hospital setting. The use and availability of gloves have increased but personal protective equipment like protective garments, face and respiratory protective, when handling chemotherapy have decreased and medical monitoring of

exposed employees still is neither widely practiced nor consistent with Occupational Safety and Health Administration (OSHA) guidelines. (**Ramanand Chaudhary, 2012**)

A prospective interventional study was conducted in a General Hospital, Malaysia a single group of 96 nurses actively participated for assessing the change of nurses' safety-related knowledge as well as attitude levels regarding cytotoxic drugs. A self-administered questionnaire and performance checklist were used. The first and second assessments took 2 months respectively with a 9-month intervention period. The study result shows that the pharmacist-based interventions improved the knowledge, attitude and safe practices of nurses in cytotoxic drug handling (7.6 ± 5.51 to 15.3 ± 2.55). It concludes that further assessment may help to confirm the sustainability of the improvement in practices. (**Chan Huan Keat, et al., 2013**)

A descriptive survey design was conducted to describe the adverse effects experienced by nurses working in chemotherapy settings Shiraz, Iran. Out of 79 eligible nurses, 63 (80%) agreed to participate in the study. Structured questionnaires were used the results shows that all nurses participated in this study had bachelor's degree they had been working as a nurse for a median of 5.5 years and in oncology wards for three years. Headache and skin reactions were the most frequent adverse effects reported by participants. None of the participants reported congenital anomalies or malignancy. Only 60% of participants reported the use of all protective equipment simultaneously; 4% did not use any protective equipment. The study finding shows that gloves and mask were the most frequent equipment used by HCWs (health care workers) in this study. Participants had an incorrect belief about protection and thus do not protect themselves appropriately. The study concludes that long-term plans should be developed on continuous training program for health care worker to protect from chemotherapy adverse effects. (**M Momeni, et al., 2012**)

An observational assessment study was conducted to determine the patterns of the cytotoxic drug spillages and the exposure of the nurses to these spillages, at Post Graduate Institute of Medical Education and Research (PGIMER) Chandigarh. Twenty two nursing personnel who were posted in the chemotherapy administration

areas participated in this study. A direct non participatory observation was carried out for one month to assess the subjects. The study finding shows that 77.3% of the nurses exposed to small spills during preparation. The common site of the spillage for more than half (52.9%) of the subjects was surface of preparation of the drug and 47% experienced spillage over both surface of preparation and the gloves worn by them. The results suggest that drug spills are common in chemotherapy administration areas. Guidelines to be followed to manage the cytotoxic drug spills in the unit and a "chemotherapy spill kit" should be made available in all the chemotherapy administration areas. **(Kumari Sunita, et al., 2008)**

A cross-sectional study was conducted by using a self-administered questionnaire among 225 oncology nurses in nine specialized cancer centers in Tehran, Iran is to evaluate the healthcare's understanding on occupational exposure to cytotoxics drugs and its side effects. The questionnaires were constructed on knowledge attitude and checklist on handling cytotoxic drugs. The results indicate 45% of nurses had adequate level of knowledge regarding risk of chemotherapy exposure. The study concludes that the level of knowledge about antineoplastic agents is high among nurses, along with the level of PPE (Personal Protective Equipment) use, medical surveillance and employee training seems to be lagging behind. However, the usages of safety measures are to be as recommended by the institution to prevent from toxic exposure. **(Abdol Ali Shahrabi, et al., 2014)**

2.4 Side effects and management of chemotherapy:

A quasi experimental study conducted in medical center, Taipei, Taiwan among 60 samples were selected to investigate the nurses skill on managing cancer symptoms data collected by using questionnaires including the symptoms distress scale, hospital anxiety and depression scale, spiritual well-being scale , social support scale at the initial assessment and one week later. Comparison between groups revealed that the degree change for edema, fatigue, dry mouth, abdominal distention and spiritual well-being in the intervention group showed significant improvement compared to the control group. The study finding indicated the hospital based palliative care team had improved the care for patients in relation to symptom

management (75%) and spiritual well-being (40%). It is concluded that in clinical practices area a good care model for patients should be implemented to promote self-worth need for the patients. **(Chi-Yin Kao, et al., 2014)**

An analytical cross sectional study carried out at Mansoura University hospitals, Egypt to identify potential risk factors that may predispose nurses to chemotherapy hazards; and evaluate available protective measures used in clinical practice. A study group of 35 oncology nurses and a control group of 29 non-oncology nurses were compared for safe behavior, use of protective measures while dealing with drugs, complaints due to drug exposure and mutagens in urine. Three tools were used in the study: a self administered questionnaire, a performance checklist to assess the practice of nurses, and Ames test for the detection of mutagens in urine. Health hazards among the study group and controls were: abortions (31.4% vs 10.3%), infertility and sub-fertility (14.3% vs 3.4%), premature labour (14.3% vs 17.2%), soft tissue injuries due to spills and splashes (14.3% vs 0.0%). Urine samples from study nurses were more mutagenic than controls (40% vs 10.3%). The study concludes that by developing protocols for nurses helps them to follow the guidelines and wear protective equipment's from exposure to cytotoxic drugs. **(Karima Elshamy et al., 2010)**

A qualitative study was conducted to investigate the factor associated with receiving fertility related information by two independent interviewers among cancer patients and professional care givers with the help of six electronic databases in those 27 were included in this review. The study finding shows that the majority of the cancer patient's (66-100%) wanted information about the impact of cancer therapy on fertility. The study concludes that the need and impacts were higher in younger and childless patients and also in patients having child bearing plans. Nurses particularly face difficulty in providing fertility related information due to additional barriers associated with limited responsibility in fertility information provision. **(Joline Goossens, et al., 2014)**

A randomized controlled study was conducted to describe the characteristics and evaluate the effectiveness of complex nursing interventions in patients receiving

chemotherapy on few electronic databases, University Hospitals Leuven, Belgium. Eleven studies were included some with considerable risk bias. Despite being heterogeneous the interventions have patient's education, symptoms effects. The study finding concludes that about 10-80% of some complex nursing intervention (for nausea, vomiting, pain, headache etc) in this systematic review produce clinically meaningful and statistically relevant reduction in symptom burden based on the available data it is not possible to make definitive conclusion about the vital parts circumstances of the target population on the interventions quality of the studies. **(Annemarie Coolbrandt, et al., 2014)**

A longitudinal study design were conducted to evaluate changes in fatigue severity in women with breast cancer among 334 women's who were scheduled for breast cancer surgery in medical center located in northern Taiwan. 200 samples were used for study purpose among them fatigue, depressive symptom and symptom distress were evaluated in women prior at 1-12 months after surgery for cancer. It was found that fatigue is higher at the third day after chemotherapy and may have another peak at 11th day for the 28 days interval treatment regimen. The study concluded that after adjusting for the effect of receipt of chemotherapy symptom distress and depressive symptom the quadratic changes pattern for fatigue became imperceptible and the fatigue level were fluctuated with the patient level. **(Hsiang-Ping Huang, et al., 2014)**

A descriptive study was conducted to investigate patient's response to chemotherapy on drugs side effects and its management in an office of three medical oncologists in a grand valley state university, Michigan, with a population of 70,000 among them 20 samples was selected based on the inclusion criteria. Chemotherapy is administered by three chemotherapy certified registered nurses employed by the physicians they were also responsible for chemotherapy teaching. The findings from this study provided valuable information (80%) about patient's response to chemotherapy teaching. The results indicated that provision of side effect management information can increase the patient's ability to manage self-care thereby reducing the suffering endured from chemotherapy treatment. The study concludes that oncology

nurses need to undergo continuous research and evaluate teaching methods which will enhance patient self-management and decrease side effects. These will ultimately minimize chemotherapy side effects and promote a higher quality of life for cancer patients. **(Kelly A. Guswiler, 1991)**

A cross-sectional study was conducted to assess the attitude, practice of nurses' and barriers regarding cancer pain management at selected health institutions offering cancer treatment in Addis Ababa city, Ethiopia. Eighty two nurses were used for data collection based upon Nurses' Knowledge and Attitudes Survey Regarding Pain (NKARSP) questionnaire. The result shows that 45(54.9%) of the study participants were from the governmental hospital and the rest 37(45.1%) respondents were from private health institutions. More than half, 53.7%, of the nurses' have a negative attitude, towards cancer pain management. Similarly 65.9% of nurses' had poor cancer pain management practice. The study concludes that some kind of effort to be taken for the improvement of educational development program like in-service education, continuing education etc for nurses who are working in cancer units will promote better skill development to take care of cancer patients. **(Rahel Nega Kassa, et al., 2013)**

A descriptive cross-sectional study was conducted among 103 oncology nurses to assess knowledge and skill on nurses about chemotherapy induced nausea and vomiting (CINV) in three Hong Kong public hospitals. Data were collected from the following areas (a) demographics, (b) assessment of CINV, (c) CINV management and (d) barriers and facilitators to good CINV practice. The results shows only a one third of respondents performed a CINV assessment before starting chemotherapy, and more than 40% reported that the use of a standardized assessment tool was uncommon. Nearly half recognized that they had inadequate knowledge of different aspects of CINV, but the majority could clearly state the most common pharmacological agents used to treat chemotherapy-induced nausea (88.3%) and vomiting (87.4%). The study concludes that the respondents perceived their knowledge on CINV prevention and management is inadequate. There is a need to adopt a standardized assessment tool, to develop a management protocol and to

introduce further professional training to meet the expanding needs of both patients and nurses. (Winnie K. W, et al., 2012)

Summary

This chapter deals with the review of literature on various areas like knowledge on chemotherapy, administration of chemotherapy, safe handling of chemotherapy, side effects and managements of chemotherapy.

CHAPTER-III

METHODOLOGY

This chapter gives a brief description of the methods adopted by the investigator for the study. The present study was designed to determine the effectiveness of knowledge and skill on intravenous chemotherapy for nurses. The study was conducted by adopting the following steps of research processes viz. research design, setting, population and sampling, sample size determination, criteria for the selection of samples, instruments and tools for measuring variables, techniques of data collection and methods of data analysis.

3.1 Research approach and design:

The research design selected for this study was one group pre and post –test design; it is a type of quasi experimental design. This design was selected to explain the relationship between chemotherapy knowledge and skill of the nurses.

$$O_1 \rightarrow X \rightarrow O_2$$

- O_1 - Pre-test
- X –Intervention
- O_2 - Post-test

Pre-test (O_1) refers to pre assessment of the staff nurses knowledge and skill regarding intravenous administration of chemotherapy. Intervention (X) refers to the structured teaching program on intravenous administration of chemotherapy for staff nurses about 30 to 45 mts. Post-test (O_2) refers to re-assessment of the same after one week using structured questionnaire and check list respectively.

3.2 Variables of the study:

3.2.1 Independent variable: The independent variable within this study was the structured teaching program on intravenous chemotherapy which was used to help the nurses to increase their knowledge about chemotherapy.

3.2.2 Dependent variable: The dependent variable of the study was the knowledge and skill of the nurses on intravenous chemotherapy administration.

3.3 Setting of the study:

The study was conducted among nurses posted in medical oncology, semiprivate and special ward, PSG Hospitals, Coimbatore. A PSG hospital has a bed strength of 1315 and it is a multi-specialty teaching hospital where the annual inpatient census for oncology is around 1099, similarly 109 inpatients were admitted per month and 3 to 4 inpatients per day. Patients were admitted on different wards like medical oncology, semiprivate and special ward. Medical oncology ward consists of 20 beds with proper ventilation facilities, refrigerator for storing chemotherapy drugs, designated area for preparing drugs and washing area for disinfecting. The semiprivate ward consists of 48 beds and the special ward consists of 20 beds with all facilities except a separate room for chemotherapy drug preparation.

3.4 Population and sampling:

The staff nurses working in medical oncology, semiprivate and special ward of PSG Hospitals were selected for study. The study samples were selected based on sampling criteria.

3.4.1 Sampling techniques:

Purposive sampling technique was used. Free sampling method was adopted for selecting the sample.

Samples:

All nurses working in medical oncology, semiprivate and the special wards. A total of 32 samples were selected.

3.4.2 Sampling criteria:

Inclusion Criteria:

- Nurses who are willing to participate in the study.
- Nurses who handle chemotherapy drugs.

3.5 Instrument and tools for data collection:

The instrument used for the collection of data was structured knowledge questionnaire and check list. The tool consist of three sections, in section A the questions were about the personal information about the sample. In section B the questions are on the knowledge on intravenous chemotherapy, section C contains a check list to assess the skill on intravenous chemotherapy.

Section A: Demographic Data (it consists of personal information such as name, age in years, gender, educational status, year of experiences)

Section B: Knowledge on Intravenous Chemotherapy

Part -1 Questions related to knowledge on chemotherapy	(7)
Part -2 Questions related to chemotherapy drugs	(8)
Part -3 Questions related to safe handling of chemotherapy drugs	(3)
Part -4 Questions related to drug administration	(7)
Part -5 Questions related to management of chemotherapy complication	(5)

Total numbers of questions were 30 each question carries one mark, total mark was 30 (**Annexure IV**)

Section C: Checklist on skill of intravenous chemotherapy (**Annexure IV**)

Part -1 Preparation of drugs	(10)
Part -2 Administration of drugs	(10)

Interpretation of score:

The level of knowledge was interpreted as follows:

Level of knowledge

Adequate knowledge	= 21-30	(67-100%)
Moderately adequate knowledge	= 11-20	(34-66%)
Inadequate knowledge	= 0-10	(0-30%)

Interpretation of score:

Check list consists of skill on intravenous chemotherapy preparation and administration.

The level of skill was interpreted as follows:

Level of skill

Highly skilled	= 27-40	(67-100%)
Moderately skilled	= 14-26	(34-66%)
Not skilled	= Less than 14	(0-33%)

3.5.1 Validity and reliability of tool:

The validity of the tool has been determined by expert opinion from different fields along with the objectives of the study. The experts were requested to give their opinion, clarity and appropriateness, suggestions for the modification of the tool and were incorporated in the final tool. The tool which was used for the study was structured questionnaires, the reliability and the practicability of the tool was tested through pilot study by using split half method. It was computed using Karl Pearson's correlation coefficient method. The reliability of the tool was found to be 0.78.

3.5.2 Technique of data collection:

Data collection was done from 29-06-2015 to 08-07-2015. The samples were selected from medical oncology, semiprivate and special ward in PSG Hospitals. Data was collected using structured questionnaire and check list.

3.5.3 Data collection procedure:

Data was collected from PSG Hospitals. Samples who met the inclusion criteria were selected by using the purposive sampling techniques for the study. After selecting the sample, data was collected through questionnaire method and check list was used to assess their skill.

Steps in data collection:

- Introduction to the research and consent was obtained from the samples.
- Collected the demographic data from the samples.
- Administered the knowledge questionnaire to the samples.
- Direct observation check list was used to assess the practice of intravenous chemotherapy preparation and administration of drugs.
- After the Pre-test observation, the required education was given with the help of computer aided tools.
- Post test was conducted with the same questionnaire.
- Direct observation check list was used to assess the changes in the skills of the samples in order to measure the effectiveness of the program.

3.6 Ethical approval:

Ethical clearance from the Institutional human ethics committee of PSGIMSR was obtained to conduct the study. A written permission was obtained from the medical oncologist of PSG Hospitals, Coimbatore. The ethical approval certificate is attached in the annexure II.

3.7 Report on the pilot study:

The pilot study was conducted to test the validity, practicability of the tool and feasibility of conducting the study. It was conducted from May 25.5.2015 to 31.5.2015 at PSG Hospitals in day care unit with the help of semi-structured questionnaires and observation checklist. Eight samples were purposively selected. The researcher conducted pre-test on both knowledge and skill on intravenous administration of chemotherapy by using semi-structured questionnaires and observation checklist.

Intervention was provided on intravenous administration of chemotherapy after exposure to the program. On the fourth day post-test was conducted with the help of the same questionnaires and observational checklist. The scores were tabulated based on the mean, standard deviation, paired 't' test, chi-square and correlation coefficient test. The 'r' value is 0.78 and the results revealed that there is a significant improvement in the knowledge and skills of the nurses regarding intravenous administration of chemotherapy.

3.7.1 Changes brought after the pilot study:

After the pilot study the questionnaire was appropriately structured and formulated.

3.8 Data analysis plan:

Descriptive statistics:

- Frequency and percentage will be used for the distribution of samples based on their knowledge and skill on intravenous chemotherapy.
- Mean and standard derivation will be used to assess pre and post-test knowledge and skill of the nurses on intravenous chemotherapy.

Inferential statistics:

- Paired 't' test will be used to evaluate the effectiveness of structured teaching program on the knowledge and skill of the nurses administering intravenous chemotherapy.
- Chi-square test will be used to find an association between pre-test evaluation of nurses regarding administration of intravenous chemotherapy and their selected demographic variables.
- Correlation and coefficient will be used to find the relationship between pre and post-test knowledge and skill of the nurses on intravenous administration of chemotherapy.

CHAPTER IV

DATA ANALYSIS AND INTERPRETATION

Data analysis is the systematic organization and synthesis of research data and testing of research hypothesis using those data. Interpretation is the process of making sense of the result of the study and examining their implications. Analysis is the method of rendering qualitative data as easily understandable and providing intelligent information about the research problem which will be helpful to study and test the relationship between the variables.

In this study, the effectiveness of structured teaching program on intravenous administration of chemotherapy was assessed. The data was collected, assembled, analyzed and tested individually and described. The findings based on the statistical analysis, presented in this chapter are.

SECTION A: Frequency and percentage distribution

1. Frequency and percentage distribution of nurses according to their demographic data.
2. Frequency and percentage distribution of nurses according to their pre and post-test knowledge scores in intravenous administration of chemotherapy.
3. Frequency and percentage distribution of nurses according to their pre and post-test skill scores on intravenous administration of chemotherapy.

SECTION B: Mean, standard deviation and mean percentage

1. Aspect wise pre and post-test knowledge scores of nurses' on intravenous administration of chemotherapy.
2. Aspect wise pre and post-test skill score of the nurses' on intravenous administration of chemotherapy.

SECTION C: Comparison of pre and post-test skill

1. Comparison between pre and post-test level of skill among nurses administering intravenous chemotherapy

SECTION D: Effectiveness of structured teaching program

1. The effectiveness of the structured teaching program on nurses practicing intravenous administration of chemotherapy.

SECTION E: Association between pre and post-test knowledge and skill and their selected demographic variables

1. Association between pre-test knowledge of nurses about intravenous administration of chemotherapy and their selected demographic variables.
2. Association between pre-test level of skill of the nurses in the intravenous administration of chemotherapy and their selected demographic variables.

SECTION F: Relationship between knowledge and skill

1. Relationship between knowledge and skill level of the nurses on intravenous administration of chemotherapy in pre and post-test.

SECTION A

This section includes the frequency and percentage distribution of nurses according to their demographic data, pre and post-test knowledge and skill scores.

Table 4.1: Frequency and percentage distribution of nurses according to their demographic data

n = 32

Demographic data	Frequency	Percentage
Age (in years)		
21-25	29	90.6
26-30	3	9.3
Above 30	0	0
Gender		
Female	32	100
Male	0	0
Educational status		
B.Sc.(N)	21	65.6
GNM	11	34.3
M.Sc.(N)	0	0
Years of experience		
Less than 2 years	24	75
2-3 years	6	18.7
Above 3 years	2	6.2
Enrollment in Chemotherapy training program		
Yes	4	12.5
No	28	87.5

Thirty two nurses were selected for the study, among them 29(90.6%) members were between the age 21-25 years, 3(9.3%) of them were 26-30 years of age. 32(100%) of them are female nurses, among them 21(65.6%) nurses have a degree in B.Sc Nursing and the remaining 11(34.3%) have a diploma in GNM. 24(75%) staff nurses have less than 2 years of experience, 6(18.7%) of them having 2-3 years and the remaining 2(6.2%) members have above 3 years of experience. 28(87.5%) nurses have not attended any training program regarding intravenous administration of chemotherapy and the remaining 4(12.5%) have undergone chemotherapy training sessions at PSG Hospital.

Table 4.2: Frequency and percentage distribution of nurses according to their pre and post-test knowledge scores on intravenous administration of chemotherapy

n=32

Level of knowledge	Pre-test		Post-test	
	Frequency	Percentage	Frequency	Percentage
Adequate knowledge	3	9.375	22	68.75
Moderately adequate knowledge	28	87.5	10	31.25
Inadequate knowledge	1	3.125	0	0

Distribution of nurses according to their level of knowledge on intravenous administration of chemotherapy shows that in pre-test 28 nurses (87.5%) had moderately adequate knowledge, 3 nurses (9.375%) had adequate knowledge and 1 nurse (3.125%) had inadequate knowledge. In the post-test 22 nurses (68.75%) had adequate knowledge and 10 nurses (31.25%) had moderately adequate knowledge after the implementation of the structured teaching program.

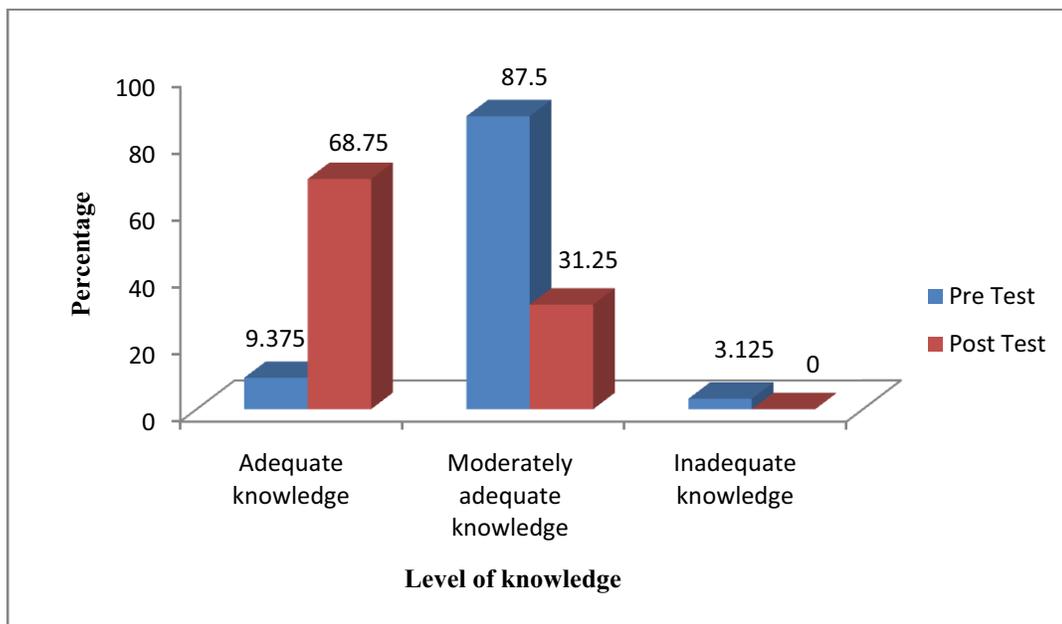


Figure4.1: Percentage distribution of nurses according to their pre and post-test knowledge scores

Table 4.3: Frequency and percentage distribution of nurses according to their pre and post-test skill scores on intravenous administration of chemotherapy

n = 32

Level of skill	Pre-test		Post-test	
	Frequency	Percentage	Frequency	Percentage
Highly skilled	3	9.375	32	100
Moderately skilled	29	90.625	0	0
Not skilled	0	0	0	0

Distribution of nurses according to their level of skill on intravenous administration of chemotherapy shows that in pre-test 29 nurses (90.625%) were moderately skilled and 3 nurses (37.5%) were highly skilled. In post-test all 32 nurses (100%) had high levels of skills after the implementation of the structured teaching program.

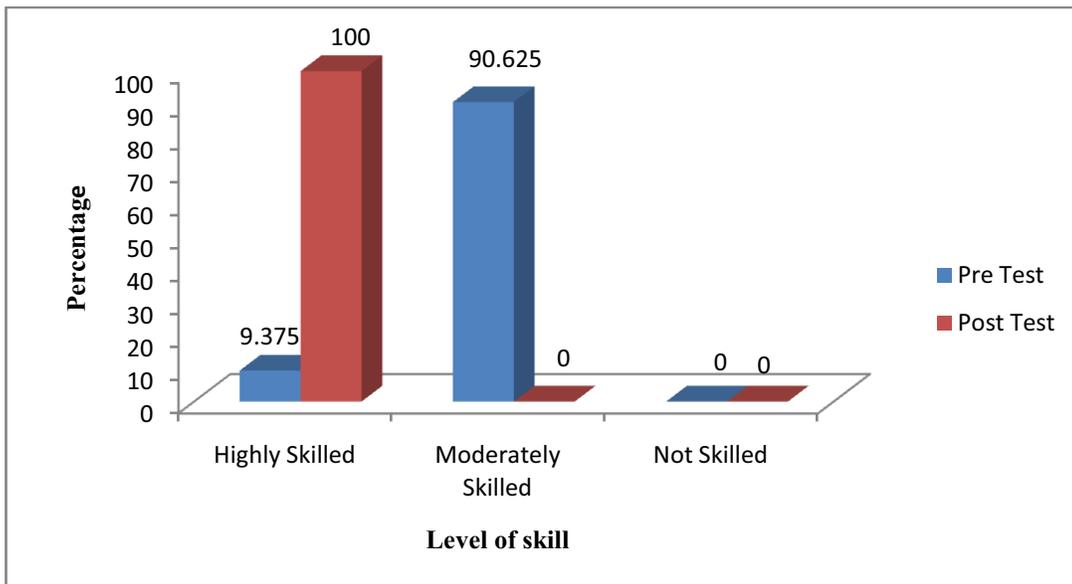


Figure 4.2: Percentage distribution of nurses according to their pre and post-test skill scores

SECTION B

This section includes aspect wise mean, standard deviation and mean percentage of nurse's knowledge and skill on intravenous administration of chemotherapy

Table 4.4: Aspect wise pre and post-test knowledge scores of nurses' on intravenous administration of chemotherapy

n = 32

Aspect	Max. Score	Pre-test			Post-test			Difference in mean percentage
		Mean	SD	Mean (%)	Mean	SD	Mean (%)	
Knowledge on chemotherapy	7	3.43	1.34	49	5.03	1.12	71.85	22.85
Chemotherapy drugs	8	5	1.27	71.4	6.56	1.45	82	10.6
Safe handling of drugs	3	2.75	0.43	91.6	3.0	0	100	8.4
Drug administration	7	2.40	1.41	34.2	4.43	1.77	63.28	29.08
Management of chemotherapy complications	5	3.09	0.85	61.8	4.03	0.78	80.6	18.8
Overall score	30	16.75	3.11	55.8	23.03	3.23	76.76	20.96

Aspect wise pre and post-test knowledge scores of the nurses' on intravenous administration of chemotherapy tabulated above, shows that out of 30 (maximum obtainable score), the mean score was 16.75 ± 3.11 which is around 55.8% of the total score, implying a moderately adequate knowledge for the nurses in pre-test where as

the post-test results show a mean score of 23.03 ± 3.23 which is around 76.76% of the total score. The overall difference in mean percentage is 20.96%, which is a significant improvement.

In regard to knowledge on chemotherapy in pre-test, the mean score was 3.43 ± 1.34 which is 49% of the total score and in post-test the mean score was 5.03 ± 1.12 which is 71.85% of total score.

Taking into account, the knowledge about chemotherapy drugs in pre-test, the mean score was 5 ± 1.27 which is 71.4 % of total score and in post-test the mean score was 6.56 ± 1.45 which is 82% of total score.

In context with knowledge on safe handling of drugs in pre-test, the mean score was 2.75 ± 0.43 which is 91.6 % of total score and in post-test the mean score was 3.0 ± 0 which is 100% of total score.

With regard to knowledge on drug administration in pre-test, the mean score was 2.40 ± 1.41 which is 34.2% of total score and in post-test the mean score was 4.43 ± 1.77 which is 63.28% of total score.

In terms of knowledge on management of chemotherapy complications, in pre-test, the mean score was 3.09 ± 0.85 which is 61.8% of total score and in post-test the mean score was 4.03 ± 0.78 which is 80.6 % of total score.

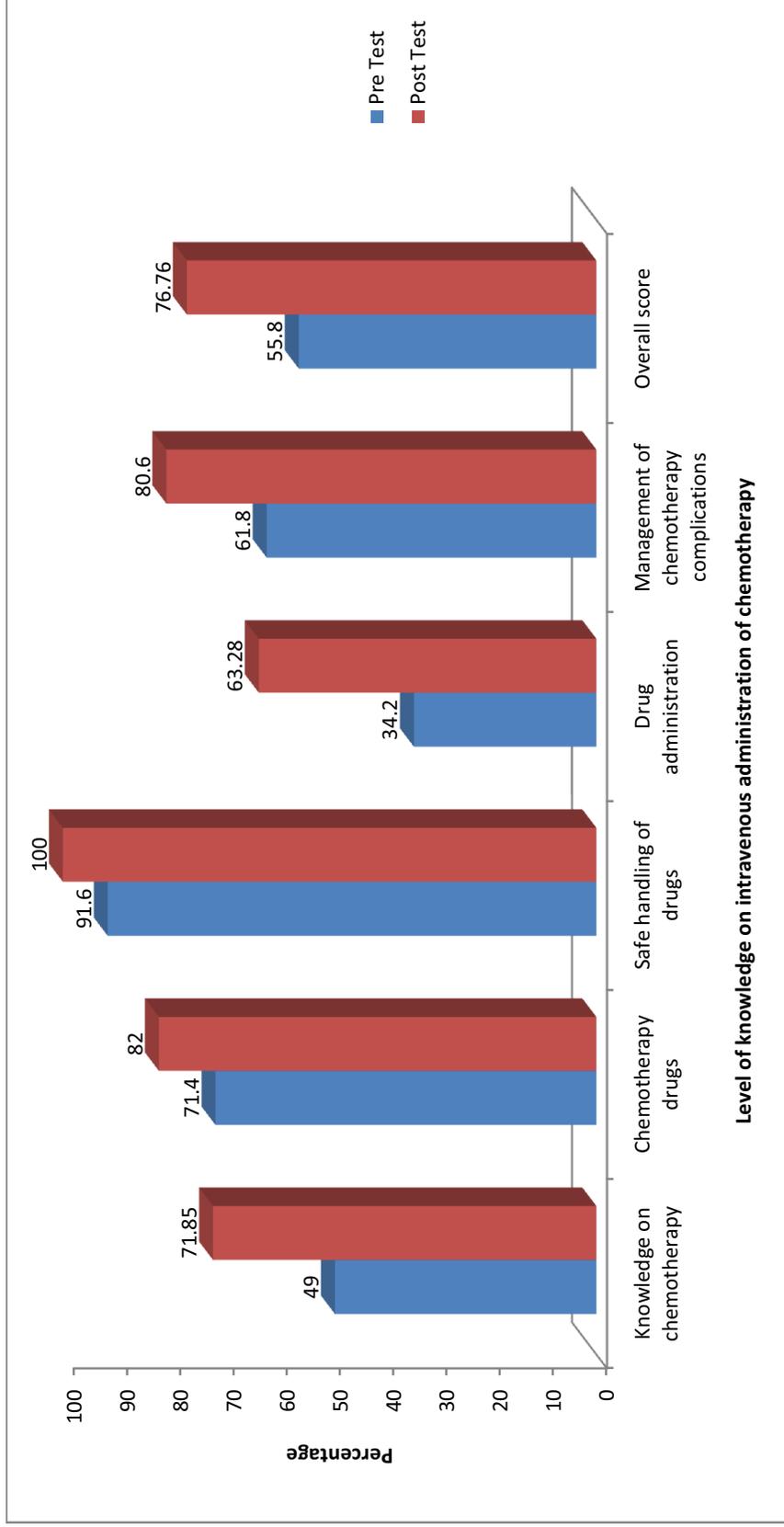


Figure 4.3: Aspect wise pre and post-test knowledge score of nurses on intravenous administration of chemotherapy

Table 4.5: Aspect wise pre and post-test skill scores of nurses' regarding intravenous administration of chemotherapy

n = 32

Aspect	Max. score	Pre-test			Post-test			Difference in mean percentage
		Mean	SD	Mean (%)	Mean	SD	Mean (%)	
Preparation of drugs	20	15.03	1.51	75.15	17.21	1.28	86.05	10.9
Administration of drugs	20	8.46	1.24	42.3	15.281	1.631	76.405	29.7
Overall score	40	23.46	2.25	58.65	32.491	2.911	81.227	22.577

Aspect wise pre and post-test skill scores of nurses' on intravenous administration of chemotherapy shows that out of 40 (maximum obtainable score), the mean score was 23.46 ± 2.25 which is 58.65% of the total score, shows a moderately skilled by the nurses in pre-test where as in post-test the mean score was 32.491 ± 2.911 which is 81.227% of the total score which shows highly skilled. The overall mean difference in percentage is 22.577%.

With regard to knowledge on preparation of drugs in pre-test, the mean score was 15.03 ± 1.51 which is 75.15 % of the total score and in post-test the mean score was 17.21 ± 1.28 which is 86.05% of total score.

In context to knowledge on administration of drugs in pre-test, the mean score was 8.46 ± 1.24 which is 42.3 % of the total score and in post-test the mean score was 15.281 ± 1.631 which is 76.405% of total score.

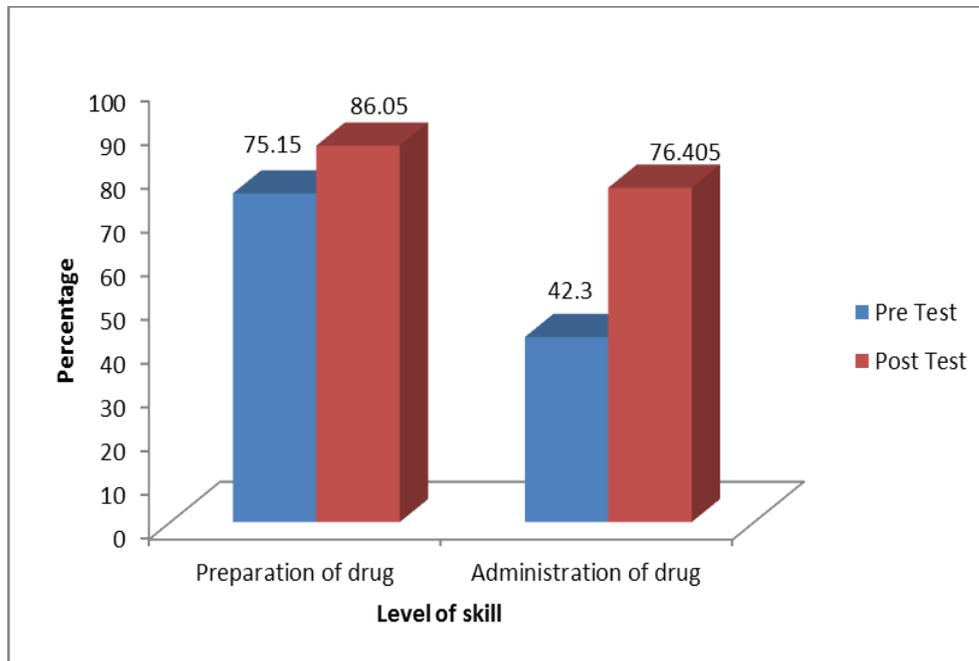


Figure 4.4: Aspect wise pre and post-test skill scores of nurses on regarding intravenous administration of chemotherapy

Table 4.6 Comparison between pre and post-test level of skill among nurses administering intravenous chemotherapy.

n= 32

S.No	Questions	Level of Skill					
		Highly Skilled		Moderately Skilled		Not Skilled	
		Pre Test f (%)	Post Test f (%)	Pre Test f (%)	Post Test f (%)	Pre Test f (%)	Post Test f (%)
Preparation of drug							
1	Assembling all equipment in procedure room	0	12 (37.5%)	24 (75%)	20 (62.5%)	8 (25%)	0
2	Washing hands before and after handling chemotherapeutic drugs	1 (3.12%)	22 (68.7%)	29 (90.6%)	10 (31.2%)	2 (6.25%)	0
3	Wearing facemask, plastic apron, goggles and gloves.	0	30 (93.7%)	31 (96.8%)	2 (6.25%)	1 (3.12%)	0
4	Removing the plastic cork of IV fluid and injection vial.	32 (100%)	32 (100%)	0	0	0	0
5	Following aseptic techniques while preparing drugs.	16 (50%)	31 (96.8%)	16 (50%)	1 (3.2%)	0	0
6	Withdrawing chemotherapy medicine by using disposable syringe and expel air without spillage of medication	9 (28.1%)	10 (31.2%)	21 (65.6%)	22 (68.7%)	2 (6.25%)	0
7	Administering of normal saline before and after chemotherapy	32 (100%)	32 (100%)	0	0	0	0
8	Discarding disposable syringe in red colour cover.	32 (100%)	32 (100%)	0	0	0	0
9	Disposing of supplies and unused drugs.	32 (100%)	32 (100%)	0	0	0	0
10	Avoiding eating, drinking, or storing food in around drug preparation area.	6 (18.7%)	15 (46.8%)	23 (71.8%)	17 (53.1%)	3 (9.37%)	2 (6.25%)

Administration of Drug							
11	Wearing protective equipment	0	30 (93.7%)	31 (96.8%)	2 (6.25%)	1 (3.12%)	0
12	Wiping stopcock with spirit swab.	0	1 (3.12%)	0	2 (6.25%)	32 (100%)	29 (90.6%)
13	Keeping absorbent cotton under stopcock to absorb any leakage of medicine.	0	20 (62.5%)	0	5 (15.6%)	32 (100%)	7(21.8%)
14	Connecting the IV tubing with the stopcock or IV cannula of the patient.	29 (90.6%)	30 (93.7%)	3 (9.37%)	2 (6.25%)	0	0
15	Informing the patient about the drug administration	0	14 (43.7%)	15 (46.8%)	18 (56.2%)	17 (53.1%)	0
16	Instructing the patient to report in case of adverse reactions	0	11 (34.3%)	8 (25%)	21 (65.6%)	24 (75%)	0
17	Disposing of all used protective equipment's in red container.	31 (96.8%)	32 (100%)	1 (3.12%)	0	0	0
18	Washing hands.	3 (9.37%)	27 (84.3%)	29 (90.6%)	5 (15.6%)	0	0
19	Observing the patient throughout intravenous chemotherapy for development of any adverse reaction.	1 (3.12%)	13 (40.6%)	24 (75%)	19 (59.3%)	7 (21.8%)	0
20	Documenting the procedure on time.	1 (3.12%)	28 (87.5%)	30 (93.7%)	4 (12.5%)	1 (3.12%)	0

Comparison between the pre-test and post-test level of skill shows that there is high improvement 22 (68.75%) in washing hands before and after handling chemotherapeutic drugs after implementing structure teaching program.

Majority of the nurses had 31(96.8%) followed aseptic technique while preparing drugs after implementing structured teaching program.

Three four of the nurses 15(46.8%) had developed high skill on avoiding eating, or storing food in drug storage area.

Majority of nurses 21(65.6%) had progressed to moderate skill on instructing patient to report about adverse effect.

Majority of the nurses 29(90.6%) had developed moderate skill on hand washing after implementing structure teaching program.

Table 4.7: The effectiveness of the structured teaching program on nurses practicing intravenous administration of chemotherapy

n = 32

Variables		Mean	SD	“t” value		P value
				Calculated value	Tabulated value	
Knowledge	Pre test	16.75	3.11	10.554*	2.040	0.00001
	Post test	23.03	3.23			
Skill	Pre test	23.46	2.25	5.24*	2.040	0.00001
	Post test	32.49	2.91			

Note: Statistically significant- * $p < 0.05$, S- significant

The effectiveness of the structured teaching program on intravenous administration of chemotherapy was measured using paired “t” test. The calculated value for pre and post-test knowledge is 10.554 and the tabulated value is 2.040 at the level of ($p < 0.05$), this shows that there is a significant improvement in the knowledge of the nurses after the implementation of structured teaching program.

With regard to pre and post-test skill level, the calculated value is 5.24 and the tabulated value is 2.040 at the level of ($p < 0.05$) and this difference shows that there is a significant improvement in the level of skill after implementing the structured teaching program.

Table 4.8: Association between pre-test knowledge of nurses about intravenous administration of chemotherapy and their selected demographic variables

n = 32

Demographic variables	Level of knowledge			Degree of freedom	Chi-square value		P value
	Adequate f (%)	Moderate f (%)	Inadequate f (%)		Calculated value	Tabulated value	
Age in years							
21- 25 years	2 (6.25%)	26 (81.2%)	1 (3.12%)	2	2.19	5.991	0.34
26-30 years	1 (3.12%)	2 (6.25%)	0				
Educational status							
B.Sc (N)	2 (6.25%)	19 (59.3%)	0	2	13.93*	5.991	0.0009
GNM	1 (3.12%)	9 (28.1%)	1 (3.12%)				
Years of experience							
Less than 2 years	2 (6.25%)	21 (65.6%)	1 (3.12%)	4	4.85	5.991	0.303
2-3 years	0	6 (18.7%)	0				
Above 3 years	1 (3.12%)	1 (3.12%)	0				
Additional chemotherapy training programs attended							
Yes	0	4 (12.5%)	0	2	0.24	5.991	0.887
No	3 (9.37%)	24 (75%)	1 (3.12%)				

Note: Statistically significant- *p<0.05, NS- Not signification, S- Signification

By using chi square test, data analysis was done to find out the association between pre-test knowledge of nurses about intravenous administration of chemotherapy and their selected demographic variables viz. age in years, educational status, years of experience and additional chemotherapy training program attended.

The results show that there is a significant association between the educational statuses and there is no significant association between age in years, year of experience and additional chemotherapy training programs attended, among nurses who administer intravenous chemotherapy.

Table 4.9: Association between pre-test level of skill of the nurses in the intravenous administration of chemotherapy and their selected demographic variables

n = 32

Demographic variables	Level of skill			Degrees of freedom	Chi-square values		P value
	Highly skilled f (%)	Moderately skilled f (%)	Not skilled f (%)		Calculated value	Tabulated value	
Age in years				2	0.03	5.991	0.99
21-25 years	3 (9.37%)	26 (81.2%)	0				
26-30 years	0	3 (9.37%)	0				
Educational status				2	0.001	5.991	0.99
B.Sc(N)	2 (6.25%)	19 (59.3%)	0				
GNM	1 (3.12%)	10 (31.2%)	0				
Years of experience				4	0.57	9.488	0.97
Less than 2 years	2 (6.25%)	22 (68.7%)	0				
2-3 years	1 (3.12%)	5 (15.6%)	0				
Above 3 years	0	2 (6.25%)	0				
Additional chemotherapy training program attended				2	1.29	5.991	0.524
Yes	1 (3.12%)	3 (9.37%)	0				
No	2 (6.25%)	26 (81.2%)	0				

Note: Statistically significant- *p< 0.05, NS – Not significant

By using chi square test, data analysis was done to find out the association between pre-test level of skill of the nurses in the intravenous administration of chemotherapy and their selected demographic variables of age in years, educational status, year of experience and additional chemotherapy training program attended.

The results show that there is no significant association between age in years, educational status, and years of experience among nurses who administer intravenous chemotherapy.

Table 4.10: Relationship between knowledge and skill level of the nurses on intravenous administration of chemotherapy in pre and post test

n = 32

Variables	Mean value	SD	“r” value
Pre-test knowledge and skill	6.718	3.65	0.12
Post-test knowledge and skill	8.625	3.94	0.10

Correlation coefficient was used to find the relationship between pre-test and post-test knowledge and skill level of nurses on intravenous administration of chemotherapy and the r value of pre-test knowledge and skill were found to be $r=0.12$ and post-test value were $r=0.10$, it shows that there is positive correlation between pre and post-test knowledge and skill of nurses on intravenous administration of chemotherapy.

CHAPTER V

RESULT AND DISCUSSION

This chapter presents a detailed discussion on the major objectives, corresponding findings and observations during the conduct of the study. These findings are also compared with the findings and observations of similar studies.

5.1 Demographic status of the nurses: The age of the nurses ranged from a minimum of 21 years to a maximum of over 30 years. A majority of 29 (90.6%) nurses who had participated in the study were in the age group between (21-25 years). The educational statuses of these nurses were B.Sc(N), GNM and M.Sc(N) and among these, 21 nurses (65.6%) had a degree in B.Sc(N). The years of experience range from less than 2 years to above 3 years, the majority in this case were 24 nurses (75%) with less than 2 years of experience. The highest number of nurses who didn't have had attended any chemotherapy training programs before the study were 28 (87.5%).

5.2 Frequency and percentage distribution of nurses according to their level of knowledge on intravenous administration of chemotherapy.

The result of this study showed an increase in level of knowledge of the nurses. 22(68.75%) had adequate knowledge and 10(37.5%) had moderately adequate knowledge after implementation of structured teaching program on intravenous administration of chemotherapy. These findings are similar to an another study, which on evaluating the nurses' knowledge on chemotherapy showed that the knowledge about chemotherapy was gained mainly from consultation with colleagues (4.0 ± 0.8) and in-hospital continuing education (3.9 ± 0.8). (Hui-Yun Yu, et al., 2013)

5.3 Frequency and percentage distribution of nurses according to their level of skill on intravenous administration of chemotherapy.

In this study, it shows that there was an increase in the level of skill on intravenous administration of chemotherapy, 32(100%) nurses had highly skilled after

the implementation of structured teaching program on intravenous administration of chemotherapy. The findings of the study was supported by an another study on occupational exposure of cytotoxic drugs and the overall results suggest that appropriate implementation of recent guidance on ward handling of cytotoxic drugs has reduced the risk of drug exposure. (E Ziegler, et al., 2002)

5.4 Aspect wise pre and post-test knowledge of nurses on intravenous administration of chemotherapy.

From this study, it shows that there was an increase in the level of knowledge of the nurses during post-test, producing a mean score of 23.03 ± 3.23 which is around 76.6% of adequate knowledge which was achieved after the implementation of structured teaching program. The study was supported by an another relative study which shows that the knowledge on medication and proper administration and handling is a prudent practice for any healthcare provider to prevent from adverse effects. (Mona Kasper, 2004)

5.5 Aspect wise pre and post-test skill scores of nurses on intravenous administration of chemotherapy.

In this study, the aspect wise mean, standard deviation and mean percentage of nurses' skill on intravenous administration of chemotherapy was found to be 31.65 ± 2.52 which is around 79.12% of the total score which shows highly skilled. The result of the study was supported by an another study conducted on cytotoxic drug spillage among nursing personnel which stresses the importance of wearing personal protective equipment while administering chemotherapeutic drugs. (Kumari Sunita, et al., 2009)

5.6 The effectiveness of structured teaching program on nurses practicing intravenous administration of chemotherapy.

In this study, the finding shows that there is an increase in the knowledge of the nurses after being exposed to the structured teaching program. The results show that

there was a significant improvement in the post-test knowledge and skill of the nurses. The results were supported by an another study which highlighted the lowering of errors on cytotoxic drugs during calculation of dosage, preparation, administration, and disposal, producing an effective improvement among nurses who had undergone an education program. **(Anna N. Vioral, 2014)**

5.7 Association between pre-test knowledge of nurses about intravenous administration of chemotherapy and their selected demographic variables.

In this study, an association was found between knowledge and selected demographic variables like age in years, educational status, years of experience and additional chemotherapy training programs attended respectively. The result was supported by an another study which shows that the majority of the nurses had adequate knowledge on chemotherapy due to educational statuses and years of experience. **(Magda M. Mohsen, et al., 2013)**

5.8 Association between pre-test level of skill of the nurses in the intravenous administration of chemotherapy and their selected demographic variables.

In this present study, no association was found between skill and selected demographic variables like age in years, educational status, year of experience and additional chemotherapy training programs attended respectively. These results were supported by an another relative study which shows that there was no association between pre-test level of skill and their demographic data. **(Hemavathy. S, 2014)**

5.9 Relationship between pre-test and post-test knowledge and skill level of the nurses on intravenous administration of chemotherapy.

In this study, the statistical analysis showed that there was correlation between pre and post-test knowledge and skill level of the nurses. This study was supported by another finding in which there was an improvement between the pre and post-test assessment after giving an education on safe handling practices helps to minimize the risk of occupational exposure for oncology nurses. **(Jennifer Lewis, 2012)**

CHAPTER VI

SUMMARY AND CONCLUSION

This study was conducted to assess the effectiveness of structured teaching program for nurses administering intravenous administration of chemotherapy. Relevant literatures were reviewed to enrich the knowledge on the selected specialization that is the intervention structured teaching, selecting an appropriate conceptual model, developing a frame work and research plan.

The research design adopted for this study was pre and post-test design, it is a type of quasi experimental design. The study was conducted in PSG Hospitals, Coimbatore. Using purposive sampling technique, 32 nurses administering intravenous chemotherapy were selected for this study.

Validity and reliability of the tool was tested through pilot study. According to the selection criteria, the nurses were selected for the study. A structured questionnaire was used to assess the knowledge level and check list was used to assess the level of skill. The data was collected after ethical approval, from 25.5.2015 to 31.5.2015. The pre-test level of knowledge and skill were assessed and structured teaching was provided for the nurses for about 30 to 45 minutes. The post-test level of knowledge and skill were assessed on the fourth day. Both the descriptive and inferential statistics were used to analyze the data. Paired “t” was used to evaluate the effectiveness of structured teaching program on intravenous administration of chemotherapy. Chi-square was used to find the association between pre-test evaluations of nurses about administration of intravenous chemotherapy and their selected demographic variables. Karl Pearson correlation coefficient was used to correlate between pre and post-test level of knowledge and skill on the same.

6.1 Major findings of the study

- More than half of the nurses 65.6% (21) had B.Sc (N) qualification.
- Majority 75% (24) of the nurses had less than two years of experience.

- Majority 87.5% (28) of the nurses had not undergone any additional chemotherapy training program.
- Majority of the nurses 87.5% (28) had moderately adequate knowledge, 9.375% (3) had adequate knowledge and 37.5% (1) had inadequate knowledge. After the structured teaching knowledge level was improved in which most of the nurses, 68.75% (22) had adequate knowledge and 31.75% (10) had moderately adequate knowledge.
- In the pre-test 90.625% (29) were moderately skilled and 9.375% (3) had adaptive practice and after structured teaching the level of skill was improved, in which all the nurses 100% (32) became highly skilled.
- The aspect wise mean, standard deviation and mean percentage of nurses shows moderately adequate knowledge in pre-test where as in post-test the mean score was 23.03 ± 3.23 which is around 76.76% adequate knowledge of the total score. The overall mean difference in percentage is 20.96%.
- The aspect wise mean, standard deviation and mean percentage of nurses' skill on intravenous administration of chemotherapy shows that the nurses were moderately skilled during pre-test where as in post-test the mean score was 31.65 ± 2.52 which is around 79.12% of the total score and it shows a highly skilled workmanship. The overall mean difference in percentage is 20.47%, which is an improvement.
- The effectiveness of structured teaching on intravenous administration of chemotherapy was proved through paired "t" test. While comparing the pre and post-test knowledge and pre and post-test skills, we find that there is significant improvement in the level of knowledge and skill after implementation of structured teaching.
- There was an association ($p < 0.05$, $\chi^2 = 5.991$) between previous knowledge on intravenous administration of chemotherapy and educational status.
- There was no association between previous skill on intravenous administration of chemotherapy and their selected demographic variables.

- The study shows a positive correlation ($r=0.12$, $r=0.10$) between pre-test and post-test level of knowledge and skill of the nurses on intravenous administration of chemotherapy.

6.2 Conclusion:

The primary responsibility of a healthcare professional is to create awareness and to provide necessary information through continuous education which will help in developing a positive attitude. In this study, majority of the nurses had moderately adequate knowledge and skills and after the structured teaching more than half of the nurses gained adequate knowledge and skills. The study found that structured teaching program on intravenous administration of chemotherapy has helped to develop additional knowledge and skills about the same. Hence, structured teaching helps the nurses to be aware of the hazardous effects of chemotherapy so they may protect themselves as well as the patients.

6.3 Nursing implications:

6.3.1 Nursing education

- Special training programs need to be incorporated in both undergraduate and graduate programs.
- Educating the staff and emphasizing the positive aspects of intravenous administration of chemotherapy and addressing their responsibilities and concerns are an essential step in the process.
- Continuous education among the staff nurses will help to promote and update their knowledge on chemotherapy and their hazardous effects.

6.3.2 Nursing practice

- The development of intravenous administration of chemotherapy program requires careful planning. Educating all the staff nurses on this aspect is very

important as it will help protect themselves from the hazardous effects of chemotherapy.

- Development of a manual or standard operating procedure (SOP) for intravenous chemotherapy.
- Certification program for intravenous chemotherapy.
- Protocol can be issued to respective wards which will help to reinforce the intravenous administration of chemotherapy.
- Staff nurses need to be educated through video aids on intravenous administration of chemotherapy.
- Nursing personnel working in different areas should be given in-service education.
- Nurses should incorporate acquired knowledge into practices that promote self-care regarding intravenous administration of chemotherapy and related adverse effects.
- "Chemotherapy spill kit" should be made available at all the chemotherapy drug administration areas to manage cytotoxic spills.

6.3.3 Nursing administration

- Provision must be made in curriculum to include education and training for student nurses to increase their knowledge and improve the attitude on safe handling of chemotherapy.
- Nurses must be educated effectively to use personal protective equipment and update their skills on administration and safe handling of chemotherapy.
- Periodical arrangement of in-service education, continuing education and training programs for staff nurses.

6.3.4 Nursing research

Research is important to enable the nurses build on existing knowledge. The results of the present study have taken supplementary knowledge from previously existing literature, the implications of which have been agreed widely. This present

study provides a baseline for future studies to construct upon and to inspire other investigators to carry out further studies to improve awareness and reduce exposure to hazardous drugs. Also, appropriate utilization of this research helps the nurses to make evidence based decisions.

6.4 Limitations

- This study was conducted only in a selected ward which imposed limitations in generalization of findings.
- It is difficult to gather all the staff nurses at the same time to conduct pre and post-test.
- No follow-up was done after the post-test due to time constraint of the participants.

6.5 Recommendations for further study

On the basis of the study the following recommendations were made.

- A similar study can be replicated on a larger sample size.
- A study can be conducted by using other strategies like booklets, pamphlets, electronic data, etc.
- A comparative study can be undertaken the control group and the experimental group.
- A comparative study can be done among staff nurses administering intravenous chemotherapy from selected hospitals.
- A comparative study can be conducted to assess the effectiveness of structured teaching and other techniques on the nurses about intravenous administration of chemotherapy.

Summary

This chapter has brought about the various implications of this study and also has provided suggestions for future studies. Effective teaching methods of this kind should be implemented to create adequate awareness among the staff nurses, which may help them to prevent themselves from hazards related to exposure to chemotherapy. Since, staff nurses are the main source of delivering care for the patients, more studies should be conducted regarding other related issues. Such types of studies will help in building improved knowledge about nursing profession.

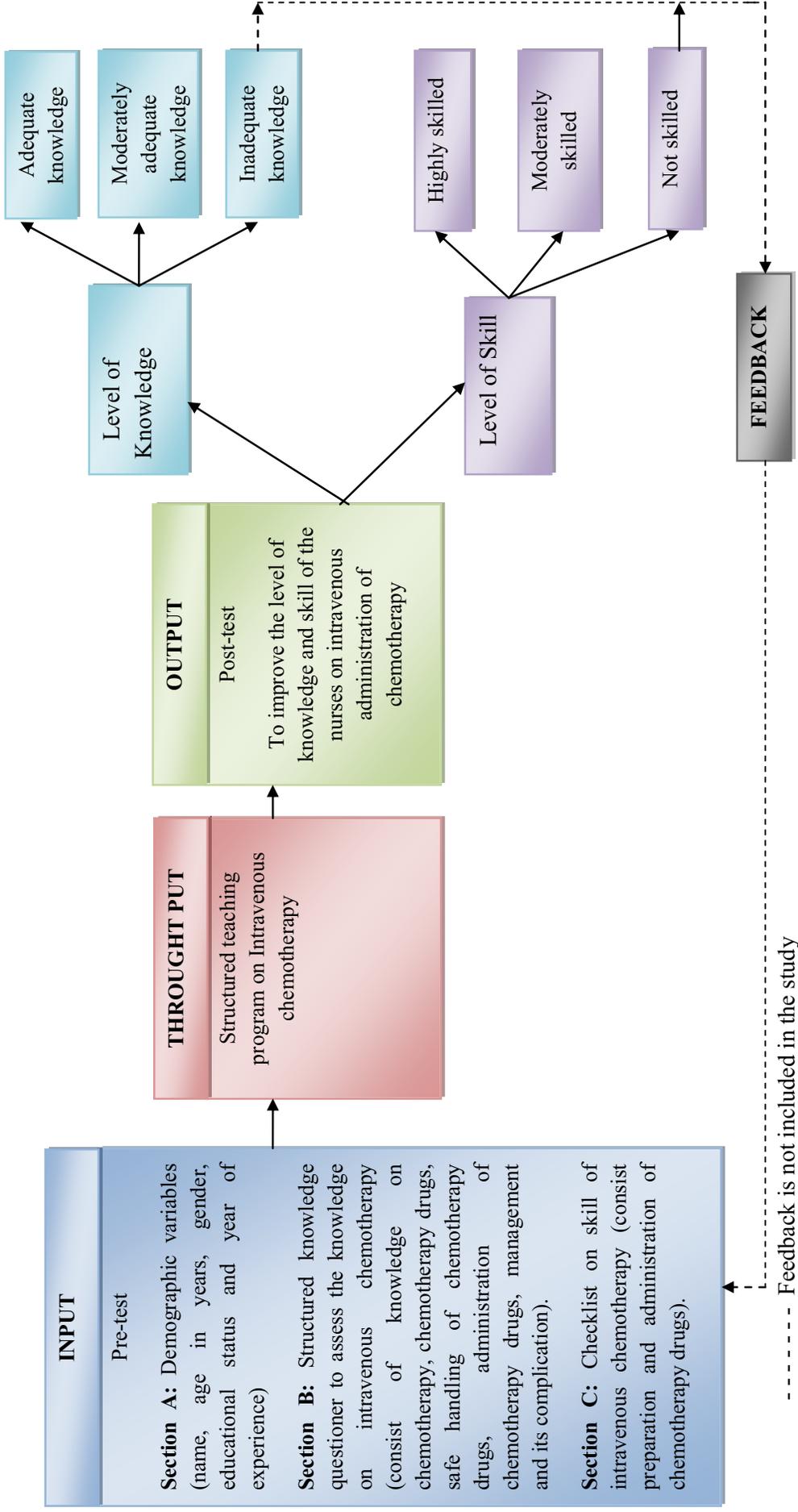


Figure No. 1.1: Based on Ludwig Von Bertalanffy (1968) modified general system model to assess the effectiveness of structured teaching program for nurses administering intravenous chemotherapy.

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ANNEXURE –I

PERMISSION LETTER

From

Ms. Praveena Arul,
I Year M. Sc Nursing,
PSG College of Nursing,
Peelamedu,
Coimbatore - 4

To

Dr. Vimal Kumar Govindan.
Medical Director,
PSG Hospitals,
Coimbatore - 4

Through : The Principal, PSG College of Nursing

Respected Sir,

**Sub: Seeking permission to carry out the study in
PSG Hospitals, Coimbatore.**

I Ms. Praveena Arul, I year M.Sc. Nursing student is interested in doing this study. "A Study on Effectiveness of Structured Teaching Program for Nurses Administering Intravenous Chemotherapy at PSG Hospitals, Coimbatore". Kindly grant me permission to carry out the study.

Thanking You,

Date: 9/2/2015
Place: Coimbatore

Yours sincerely

Praveena Arul

Ms. Praveena Arul,
I year M.Sc Nursing.

Signature of Medical Director:

[Signature]
Dr.Vimal Kumar Govindan,MS,FRCsed.,
Medical Director
PSG Hospitals
Peelamedu,
Coimbatore - 641 004.

PERMISSION LETTER

From

Ms. Praveena Arul,
I Year M. Sc Nursing,
PSG College of Nursing,
Peelamedu,
Coimbatore - 4

To

Dr. Subhash John, MBBS, DNB
Consultant, Clinical Oncologist,
PSG Hospitals,
Coimbatore - 4

Through : The Principal, PSG College of Nursing



Respected Sir,

**Sub: Seeking permission to carry out the study in
PSG Hospitals, Coimbatore.**

I Ms. Praveena Arul, I year M.Sc. Nursing student is interested in doing this study. "A Study on Effectiveness of Structured Teaching Program for Nurses Administering Intravenous Chemotherapy at PSG Hospitals, Coimbatore". Kindly grant me permission to carry out the study.

Thanking You,

Date:

Place:

Yours sincerely
Praveena Arul.
Ms. Praveena Arul,
I year M.Sc Nursing.

Signature:



**Dr. SUBHASH JOHN, DMRT, DNB.,
CLINICAL ONCOLOGIST,
PSG HOSPITALS,
PEELAMEDU, COIMBATORE-4.**

PERMISSION LETTER

From

Ms. Praveena Arul,
I Year M. Sc Nursing,
PSG College of Nursing,
Peelamedu,
Coimbatore - 4

To

Mrs. Malliga. S.
Nursing Superintendent,
PSG Hospitals,
Coimbatore - 4

Through : The Principal, PSG College of Nursing

Respected Sir,

**Sub: Seeking permission to carry out the study in
PSG Hospitals, Coimbatore.**

I Ms. Praveena Arul, I year M.Sc. Nursing student is interested in doing this study. "A Study on Effectiveness of Structured Teaching Program for Nurses Administering Intravenous Chemotherapy at PSG Hospitals, Coimbatore". Kindly grant me permission to carry out the study.

Thanking You,

Date: 9/2/2015
Place: Coimbatore

Yours sincerely

Praveena Arul

Ms. Praveena Arul,
I year M.Sc Nursing.

Signature of Nursing Superintendent:



ANNEXURE –II



PSG Institute of Medical Sciences & Research Institutional Human Ethics Committee

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
POST BOX NO. 1674, PEELAMEDU, COIMBATORE 641 004, TAMIL NADU, INDIA
Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

To
Ms Praveena Arul
I M Sc Nursing
PSG College of Nursing
Coimbatore

Ref: Project No.15/090

Date: February 27, 2015

Dear Ms Praveena Arul,

Institutional Human Ethics Committee, PSG IMS&R reviewed and discussed your application dated 18.02.2015 to conduct the research study entitled "A study on effectiveness of structured teaching program for nurses administering intravenous chemotherapy at PSG Hospitals, Coimbatore" during the IHEC meeting held on 27.02.2015.

The following documents were reviewed and approved:

1. Project Submission form
2. Study protocol
3. Informed consent form
4. Data collection tool
5. Permission letter from concerned Heads of Department
6. Current CVs of Principal investigator, Co-investigator
7. Budget

The following members of the Institutional Human Ethics Committee (IHEC) were present at the meeting held on 27.02.2015 at IHEC Secretariat, PSG IMS & R between 10.00 am and 11.00 am:

Sl. No.	Name of the Member of IHEC	Qualification	Area of Expertise	Gender	Affiliation to the Institution Yes/No	Present at the meeting Yes/No
1	Dr. P. Sathyan (Chairperson, IHEC)	DO, DNB	Clinician (Ophthalmology)	Male	No	Yes
2	Dr. S. Bhuvaneshwari (Member-Secretary, IHEC)	MD	Clinical Pharmacology	Female	Yes	Yes
3	Dr. S.Shanthakumari	MD	Pathology, Ethicist	Female	Yes	Yes
4	Dr. D. Vijaya	M Sc, Ph D	Basic Medical Sciences (Biochemistry)	Female	Yes	Yes

The study is approved in its presented form. The decision was arrived at through consensus. Neither PI nor any of proposed study team members were present during the decision making of the IHEC. The IHEC functions in accordance with the ICH-GCP/ICMR/Schedule Y guidelines. The approval is valid until one year from the date of sanction. You may make a written request for renewal / extension of the validity, along with the submission of status report as decided by the IHEC.



PSG Institute of Medical Sciences & Research

Recognized by The Strategic Initiative for Developing Capacity in Ethical Review (SIDCER)
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Phone : 91 422 - 2598822, 2570170, Fax : 91 422 - 2594400, Email : ihec@psgimsr.ac.in

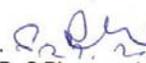
Following points must be noted:

1. IHEC should be informed of the date of initiation of the study
2. Status report of the study should be submitted to the IHEC every 12 months
3. PI and other investigators should co-operate fully with IHEC, who will monitor the trial from time to time
4. At the time of PI's retirement/intention to leave the institute, study responsibility should be transferred to a colleague after obtaining clearance from HOD, Status report, including accounts details should be submitted to IHEC and extramural sponsors
5. In case of any new information or any SAE, which could affect any study, must be informed to IHEC and sponsors. The PI should report SAEs occurred for IHEC approved studies within 7 days of the occurrence of the SAE. If the SAE is 'Death', the IHEC Secretariat will receive the SAE reporting form within 24 hours of the occurrence
6. In the event of any protocol amendments, IHEC must be informed and the amendments should be highlighted in clear terms as follows:
 - a. The exact alteration/amendment should be specified and indicated where the amendment occurred in the original project. (Page no. Clause no. etc.)
 - b. Alteration in the budgetary status should be clearly indicated and the revised budget form should be submitted
 - c. If the amendments require a change in the consent form, the copy of revised Consent Form should be submitted to Ethics Committee for approval
 - d. If the amendment demands a re-look at the toxicity or side effects to patients, the same should be documented
 - e. If there are any amendments in the trial design, these must be incorporated in the protocol, and other study documents. These revised documents should be submitted for approval of the IHEC and only then can they be implemented
 - f. Any deviation-Violation/waiver in the protocol must be informed to the IHEC within the stipulated period for review
7. Final report along with summary of findings and presentations/publications if any on closure of the study should be submitted to IHEC

Kindly note this approval is subject to ratification in the forthcoming full board review meeting of the IHEC.

Thanking You,

Yours Sincerely,


Dr S Bhuvaneshwar
Member - Secretary
Institutional Human Ethics Committee



ANNEXURE –III

PSG Institute of Medical Science and Research, Coimbatore

Institutional Human Ethics Committee

INFORMED CONSENT FORMAT FOR RESEARCH PROJECTS

(strike off items that are not applicable)

Healthy participants information sheet

I Praveena Arul, am carrying out a study on the topic: A STUDY ON EFFECTIVENESS OF STRUCTURED TEACHING PROGRAM FOR NURSES ADMINISTERING INTRAVENOUS CHEMOTHERAPY AT PSG HOSPITALS, COIMBATORE as part of my research project being carried out under the aegis of the Department of: Nursing.

My research guide is: Dr. Elizabeth Jean Abraham, Principal PSG College of Nursing / DR.G.Malarvizhi, Vice Principal PSG College of Nursing

Justification for the study:

Nurses must be aware of safe handling of the chemotherapeutic drugs which include assessment of drug preparation, administration and disposal. It is clear that nurses remain at risk of exposure. Even though they are been aware about the problem but fails to practice it in clinical area. Hence nurses been knowingly affecting them self and patients too.

The objectives of this study are:

Primary Objective:

- Assess the existing knowledge among nurses administering intravenous chemotherapy.
- Assess the skill among nurses administering intravenous chemotherapy.

Secondary Objective:

- Evaluate the effectiveness of structured teaching program on knowledge and skill among nurses administering intravenous chemotherapy.
- Find an association between pretest evaluation of nurses regarding administration of intravenous chemotherapy and their selected demographic variables.

Sample size:30.

Study volunteers / participants are (specify population group & age group): Nurses who are administering intravenous chemotherapy.

Location: PSG Hospitals, Coimbatore

I request you to kindly cooperate with me in this study. We propose collect background information and other relevant details related to this study. We will be carrying out:

Data collected will be stored for a period of 5 years. We will / will not use the data as part of another study.

Benefits from this study: Structured teaching program can increase knowledge and skill among nurses administering intravenous chemotherapy

Projected outcome of the study: Structured teaching program could help to improve the knowledge, skill of nurses who administering intravenous chemotherapy.

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI: 9629578720

Contact number of Ethics Committee Office: 0422 2570170 Extn.: 5818

INFORMED CONCERN FOR HEALTHY PARTICIPANT'S

The above information regarding the study, has been read by me/ read to me, and has been explained to me by the investigator/s. Having understood the same, I hereby give my consent to them to interview me. I am affixing my signature / left thumb impression to indicate my consent and willingness to participate in this study (i.e., willingly abide by the project requirements).

Signature / Left thumb impression of the Study Volunteer / Legal Representative:

Signature of the Interviewer with date:

Witness:

Contact number of PI:9629578720

Contact number of Ethics Committee Office: 0422 2570170 Extn.: 5818

ஓப்புதல் படிவம்

தேதி :

பிரவீனா அருள், ஆகிய நான், பி. எஸ். ஜி. மருத்துவக் கல்லூரியின், செவிலியர் துறையின் கீழ், ஹீமோதெரபி மருந்தை நரம்பு வழியாக செலுத்தும் முறையை கற்றுக்கொடுத்தல் மூலம் செவிலியரின் அறிவுத்திறனை வளர்த்தல்” என்ற தலைப்பில் ஆய்வு மேற்கொள்ள உள்ளேன்.

என் ஆய்வு வழிகாட்டி: டாக்டர். எலிசெபத் ஜீன் ஆப்ரஹாம்

ஆய்வு மேற்கொள்வதற்கான அடிப்படை:

ஹீமோதெரபி பற்றி செவிலியர்களுக்கு போதுமான அறிவு இருந்தாலும் அவற்றை நடைமுறை படுத்துவதின் முக்கியத்துவம் குறைந்துள்ளது. ஹீமோதெரபியை தவறாக கையாண்டால் செவிலியர்களுக்கு மட்டுமல்ல நோயாளிகளுக்கும் பக்க விளைவுகள் அதிகம்.

ஆய்வின் நோக்கம்:

- ஹீமோதெரபி மருந்தை நரம்பு வழியாக செலுத்தும் அறிவுத்திறனை செவிலியர்களிடையே கண்டறிதல்.
- ஹீமோதெரபி மருந்தை நரம்பு வழியாக செலுத்தும் திறனை செவிலியர்களிடையே கண்டறிதல்.
- ஹீமோதெரபி மருந்தை நரம்பு வழியாக செலுத்தும் முறையை பற்றி கற்றுக்கொடுத்தலின் பின்பாக செவிலியரின் அறிவு மற்றும் திறன் வளர்ச்சியை கண்டறிதல்.

ஆய்வில் பங்கு பெறும் நபர்களின் எண்ணிக்கை: 30

ஆய்வு மேற்கொள்ளும் இடம்: பி. எஸ். ஜி. மருத்துவமனை, கோயம்புத்தூர்.

ஆய்வின் பலன்கள்:

ஹீமோதெரபி மருந்தை நரம்பு வழியாக செலுத்தும் முறையை கற்றுக்கொடுத்ததின் மூலமாக செவிலியரின் அறிவு மற்றும் திறனில் முன்னேற்றம் ஏற்படும்.

ஆய்வினால் ஏற்படும் அசௌகரியங்கள் / பக்க விளைவுகள்: இந்த ஆராய்ச்சியின் மூலம் காயங்கள் ஏற்பட வாய்ப்புள்ளது. காயங்களை தடுப்பதற்காக பயிற்சியாளரும் பங்கு பெறுபவரின் உறவினரும் உடன் இருப்பார்கள்

இந்த ஆய்வில் கிடைக்கும் தகவல்கள் 5 வருடங்கள் பாதுகாக்கப்படும். இவை வேறு எந்த ஆய்விற்கும் பயன்படுத்தப்பட மாட்டாது. எந்த நிலையிலும் உங்களைப் பற்றிய தகவல்கள் யாருக்கும் தெரிவிக்கப்படமாட்டாது. அவை இரகசியமாக வைக்கப்படும்.

எந்த நேரத்தில் வேண்டுமானாலும் ஆய்விலிருந்து விலகிக்கொள்ளும் உரிமை உங்களுக்கு உண்டு. ஆய்விலிருந்து விலகிக்கொள்வதால் உங்களுக்கு அளிக்கப்படும் சிகிச்சையில் எந்த வித மாற்றமும் இருக்காது.

இந்த ஆராய்ச்சிக்காக உங்களிடம் சில கேள்விகள் கேட்கப்படும்.

மேலும், இந்த ஆய்வில் பங்கு கொள்வது உங்கள் சொந்த விருப்பம். இதில் எந்த விதக் கட்டாயமும் இல்லை. நீங்கள் விருப்பப் பட்டால், இந்த ஆய்வின் முடிவுகள் உங்களுக்குத் தெரியப் படுத்தப்படும்.

ஆய்வாளரின் கையொப்பம் :

தேதி :

ஆய்வுக்குட்படுபவரின் ஒப்புதல் படிவம்

நான் இந்த ஆராய்ச்சியின் நோக்கம் மற்றும் அதன் பயன்பாட்டினைப் பற்றி தெளிவாகவும், விளக்கமாகவும் தெரியப்படுத்தப் பட்டுள்ளேன். இந்த ஆராய்ச்சியில் பங்கு கொள்ளவும், இந்த ஆராய்ச்சியின் மருத்துவ ரீதியான குறிப்புகளை வரும் காலத்திலும் உபயோகப்படுத்திக் கொள்ளவும் முழு மனதுடன் சம்மதிக்கிறேன்.

ஆய்வுக்குட்படுபவரின் பெயர், முகவரி:

கையொப்பம்:

தேதி:

ஆய்வாளரின் தொலைபேசி எண்: 9629578720

மனித நெறிமுறைக் குழு அலுவலகத்தின் தொலைபேசி எண்: 0422 2570170 Extn.: 5818

ANNEXURE - IV

INSTRUMENT AND TOOL FOR DATA COLLECTION

SECTION A: DEMOGRAPHIC DATA (it consist of personal information such as name, age in years, gender, educational status, year of experiences)

SECTION B: KNOWLEDGE ON INTRAVENOUS CHEMOTHERAPY

Part -1 Questions related to knowledge on chemotherapy	-	7
Part -2 Questions related to chemotherapy drugs	-	8
Part -3 Questions related to safe handling of chemotherapy drugs	-	3
Part -4 Questions related to drug administration	-	7
Part -5 Questions related to management of chemotherapy complication	-	5

Total number of questions is 30 each question carries one mark total mark is 30

SECTION C: CHECKLIST ON SKILL OF INTRAVENOUS CHEMOTHERAPY

Part -1 Preparation of drugs	-	10
Part -2 Administration of drugs	-	10

Interpretation and scoring:

The level of knowledge is interpreted as follows:

Sl.no	Level of knowledge	Score	Percentage
1	Adequate knowledge	21-30	67-100%
2	Moderately knowledge	11-20	34- 66%
3	Inadequate knowledge	0-10	0 -30%

Interpretation and scoring: Check list on skill of intravenous chemotherapy preparation and administration.

The level of skill is interpreted as follows:

Sl.no	Level of skill	Score	Percentage
1	Highly skilled	27-40	67-100%
2	Moderately skilled	14-26	34-66%
3	Not skilled	Less than 14	0-33%

SECTION-A: Demographic Data:

Questions related to personal information put tick on the option which is fit for you.

- 1. Name :
- 2. Age in years :
 - a) 21-25 b) 26-30 c) Above 30
- 3. Gender :
 - a) Female b) Male
- 4. Educational status :
 - a) B.Sc. (N) b) GNM c) M.Sc. (N)
- 5. Year of experiences :
 - a) Less than 2years b) 2-3years c) Above 3 years
- 6. Have you attended any additional training program on IV chemotherapy?
 - a) Yes b) No

If yes, specify

- a) When :
- b) Where :
- c) Duration of the program :

SECTION –B: Structured knowledge questionnaires on intravenous chemotherapy

Structured knowledge questionnaires to assess the knowledge of nurses on intravenous chemotherapy

[Please place a tick (✓) sign in the respective box against the correct answer. There is only one correct answer]

Part- 1: Questions related to knowledge on chemotherapy

- 1. What is the action of chemotherapy?
 - a) The drug that controls tumor growth ()
 - b) The drug that reduce blood glucose level ()
 - c) The drug that improve immunity ()
 - d) The drug that increase the size of the cells ()

2. How many phases are there in the formation of cell cycle pattern?
- a) 1
 - b) 3
 - c) 5
 - d) 7
3. Which one of the following is known as resting or dormant phase in cell cycle?
- a) G0 phase
 - b) G1 phase
 - c) G2 phase
 - d) S phase
4. Which phase is known as Pre-mitotic phase?
- a) G1 phase
 - b) G2 phase
 - c) M phase
 - d) S phase
5. Which one of the following therapy shows effective response towards cancer cell?
- a) Adjuvant therapy
 - b) Neo adjuvant therapy
 - c) Combination therapy
 - d) Primary therapy
6. Which is the ideal time interval between each chemotherapy cycle?
- a) 1 week
 - b) 10-15 days
 - c) 15-20 days
 - d) 21-28 days
7. Which one of the following interferes with DNA synthesis?
- a) Antitumor agent
 - b) Alkylating agent
 - c) Antimetabolic agent
 - d) Topoisomerase inhibitors

Part-2 Questions related to chemotherapy drugs

8. Which among the following is to be administered before and after chemotherapy?
- a) 5%Dextrose solution
 - b) Ringer lactate solution
 - c) 0.9%Normal saline
 - d) 10% Glucose
9. Which one of the following IV fluid is used to dilute Inj. Cisplatin?
- a) Ringer lactate
 - b) 5% Dextrose
 - c) Normal saline
 - d) 10% Glucose
10. Which one of the following drug is known to cause peripheral toxicity?
- a) Vinblastine
 - b) 5-Flurouracial
 - c) Leucovorin
 - d) Cyclophosphamide
11. Which drug causes pulmonary toxicity?
- a) Inj. Methotrexate
 - b) Inj. Cisplatin
 - c) Inj. Vincristine
 - d) Inj. Bleomycin
12. Which is the only route for administering Inj. Doxorubicin?
- a) Sub cutaneous
 - b) Intra muscular
 - c) Intra venous
 - d) Intra thecal
13. Which one of the following drug, would you expect to find red color changes in urine?
- a) Inj. Carboplatin
 - b) Inj. 5-Fluorouracil
 - c) Inj. Daunorubicin
 - d) Inj. Leucovorin

14. Which one the following system gets easily affected by chemotherapy?
- a) Integumentary system ()
 - b) Neurological system ()
 - c) Cardiovascular system ()
 - d) Respiratory system ()
15. Which one the following symptom shows main cause for toxicity related to chemotherapy?
- a) High concentration of drug in blood ()
 - b) Decrease renal function ()
 - c) Decrease liver function ()
 - d) Nutritional deficiency ()

Part-3 Questions related to safe handling of chemotherapy drugs

16. Which are the following is expected to don by the nurse while preparing chemotherapy?
- a) Gloves and Gown ()
 - b) Goggles and mask ()
 - c) Both a & b ()
 - d) Boots ()
17. Which container is used to dispose chemotherapy glass waste (ampules and vial)?
- a) Yellow container ()
 - b) Green container ()
 - c) Red container ()
 - d) Black container ()
18. What is the ideal time limit to clean up the spillage site of chemotherapy drugs during preparation?
- a) Immediately ()
 - b) Within 5-10 minutes ()
 - c) Within 20 minutes ()
 - d) Within 30 minutes ()

Part-4 Questions related to drug administration

19. Which variable is taken for calculating intravenous chemotherapy?
- a) Body surface area ()
 - b) Vital signs ()
 - c) Age ()
 - d) Volume of the drug ()
20. Which one of the following site has least risk for extravasation?
- a) Wrist ()
 - b) Forearm ()
 - c) Antecubital fossa ()
 - d) Median cubital ()
21. What is the recommended needle size for IV chemotherapy in adult?
- a) 16 gauge ()
 - b) 18 gauge ()
 - c) 23 gauge ()
 - d) 26 gauge ()
22. What need to be considered by the nurse while administering high dose of Inj. Methotrexate therapy?
- a) Maintain an acidic urine ()
 - b) Restrict IV fluids ()
 - c) Providing a diet high in folic acid ()
 - d) Monitoring plasma level ()
23. What kind of side effect should the nurse monitor on patient who is receiving alkylating agent when returns to the oncology clinic for a follow up visit?
- a) Vomiting ()
 - b) Constipation ()
 - c) Leukopenia ()
 - d) Photosensitivity ()

24. What is the response of the nurse, if the patient asks about the reason for developing pancytopenia during the course of chemotherapy?

- a) Steroid hormones have a depressant effect on the spleen and bone marrow ()
- b) Non-cancerous cells also are susceptible to the effects of chemotherapeutic drugs ()
- c) Lymph node activity is depressed by radiation therapy used prior to chemotherapy ()
- d) Dehydration caused by nausea, vomiting and diarrhea result in hemoconcentration ()

25. A 32 years old women with stage III B Hodgkin's disease is started on bleomycin therapy, what response to the chemotherapy should the nurse teach the patient to report immediately?

- a) Fever ()
- b) Sore in mouth ()
- c) Moderate diarrhea ()
- d) Nausea ()

Part -5 Questions related to management of chemotherapy complication

26. What is the first step a nurse should take in case of an extravasation?

- a) Administer Inj. Hydrocortisone ()
- b) Stop IV flow ()
- c) Provide cold compression ()
- d) Elevate the body part ()

27. What is the initial management for hypersensitivity reaction?

- a) Administration Inj. Pantoprazole ()
- b) Administration Inj. Paracetamol ()
- c) Administration Inj. Epinephrine ()
- d) Administration Inj. Hydrocortisone ()

28. Which one of the following drug is used for managing cardiac toxicity?

- a) Administer Inj. Amoxicillin ()
- b) Administer Inj. Potassium chloride ()
- c) Administer Inj. Digitalis ()
- d) Administer Inj. Pantoprazole ()

29. Which drug is recommended for treating pulmonary toxicity?
- a) Inj. Prednisone ()
- b) Inj. Amoxicillin ()
- c) Inj. Potassium chloride ()
- d) Inj. Chloropherramine malate ()
30. In which condition Inj. Sodium bicarbonate is administered to the patient who is receiving chemotherapy?
- a) Cardiac toxicity ()
- b) Neuro toxicity ()
- c) Renal toxicity ()
- d) Hepatic toxicity ()

SECTION –C: Check list to assess nurse’s skill on administration of intravenous chemotherapy.

[Observe the skill of nurse’s during the procedure from starting to the end and put tick mark on respective column given according to the performance)

SL. NO	CONTENT	Highly skilled (2)	Moderately skilled (1)	Not skilled (0)
PREPARATION OF DRUG				
1	Assembling all equipment in procedure room (IV bottle/bag, disposable syringe, IV tubing, chemotherapeutic drug, face mask, plastic apron, goggles and gloves).			
2	Washing hands before and after handling chemotherapeutic drugs.			
3	Wearing facemask, plastic apron, goggles and gloves.			
4	Removing the plastic cork of IV fluid and injection vial.			
5	Following aseptic techniques while preparing drugs.			
6	Withdrawing chemotherapy medicine by using disposable syringe and expel air without spillage of medication.			

7	Administering of normal saline before and after chemotherapy.			
8	Discarding disposable syringe in red colour cover.			
9	Disposing of supplies and unused drugs.			
10	Avoiding eating, drinking, or storing food in around drug preparation area.			
ADMINISTRATION OF DRUGS				
11	Wearing protective equipment (Gloves, Apron, Goggles and Mask).			
12	Wiping stopcock with spirit swab.			
13	Keeping absorbent cotton under stopcock to absorb any leakage of medicine.			
14	Connecting the IV tubing with the stopcock or IV cannula of the patient.			
15	Informing the patient about the drug administration.			
16	Instructing the patient to report in case of adverse reactions (pain over the site, hypersensitivity reaction like itching, swelling, redness, nausea, vomiting etc.)			
17	Disposing of all used protective equipment's in red container.			
18	Washing hands.			
19	Observing the patient throughout intravenous chemotherapy for development of any adverse reaction.			
20	Documenting the procedure on time.			
	TOTAL			