

TO STUDY THE EFFECT OF CHEMOTHERAPY ON HEALTHCARE PRACTITIONERS

Dissertation Submitted to



for the partial fulfillment for the award of the degree of

Master of Business Administration (MBA)

in

Pharmaceutical Management

by

Mr. Debasis Das

Under the Supervision and Guidance of

Dr. Ashok Peepliwal

Associate professor, School of Pharmaceutical management IIHMR
university, Jaipur-302029

2022

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DECLARATION BY STUDENT

I hereby declare that this dissertation titled **To Study The Effect Of Chemotherapy On Healthcare Practitioners** is the bonafide record of my original research work. I declare that it has not been submitted to any other university or institution for the award of any degree or diploma. Information derived from the published or unpublished work of others has been duly acknowledged in the text.

(Signature)

Name of the student- Mr. Debasis Das

Date- 20/07/2022

CERTIFICATE

This is to certify that Debasis Das in partial fulfillment of the requirements for the award of the degree of MBA (Pharmaceutical Management) from the IIHMR University, Jaipur has successfully completed her/his internship at IIHMR University during March 22, 2022, to June 19, 2022.

Place: Jaipur
Date: 20/07/2022

Preceptor/Head of the Organization
IIHMR University

CERTIFICATE

This is to certify that dissertation titled **To Study The Effect Of Chemotherapy On Healthcare Practitioners** is a record of the research work undertaken by **Mr. Debasis Das** in partial fulfillment of the requirements for the award of the degree of MBA in Pharmaceutical Management from the IIHMR University, Jaipur under my guidance and supervision and his/her approach to the research study has been sincere, scientific, and analytical.

Dr. Ashok Peepliwal
Associate professor,
IIHMR University, Jaipur
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Date 20/07/2022

ABSTRACT

Cancer is a disease in which uncontrolled cell growth occurs due to genetic mutations or any damage in the DNA. Normal cell when come in contact with other cell during division then it stops dividing, this is called contact inhibition which a cancer cell lacks and this happens because of genetic mutation which can be done by many factors such as radiations, chemicals, fine particulate matter etc. Agents which cause cancer are known as carcinogens Benign is not much harmful but malignant is fatal because benign does not spread but malignant grow and spread into other parts of the body and this process is known as metastasis.

To diagnose a cancer there are many options available but the most accurate is the examination of the biopsy sample of the suspected tissue, stage of cancer in the body is determined by this biopsy test which determine the extent of cancer spread in the body and also tells about its severity and accordingly treatment protocol begins. The treatment of cancer includes many procedures like surgery, chemotherapy and radiation therapy

Although cancer can be cured by many procedures such as surgery, radiotherapy, bone marrow transplant, immunotherapy, targeted drug therapy but one of the famous procedure or therapy is chemotherapy. In chemotherapy cytotoxic drugs are used that are toxic to cells to kill cancer cells.

And these cytotoxic drugs are very harmful for normal beings also. So it is very necessary to take precautions and safety measures during the dispensing, administration, handling and disposal of these drugs.

In an oncology department where healthcare providers are working in order to treat cancer patients are coming in contact of these drugs on daily basis. And due to this contact with these drugs there are chances of developing health related issues in these healthcare professionals like skin and throat irritations, allergic reactions, headaches, hair loss, nausea, vomiting, diarrhoea, congenital defects, infertility and even in some cases it increases the chances of developing a cancer.

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ABSTRACT

This study examines how cytotoxic medications affect cancer patients who are receiving chemotherapy to treat their cancer cells. These cytotoxic medications pose serious risks to both healthy people and medical professionals who use them on a daily basis to treat patients.

These cytotoxic medications can have both short-term and long-term effects on healthcare professionals, including hair loss, skin irritation, eye irritation, nausea, hearing loss, heart toxicity, renal damage, infertility, and effects on developing embryos.

Who is most at risk? Anyone handling these cytotoxic medications, such as surgeons, doctors, nurses, pharmacy technicians, and pharmacists, is more likely to be exposed. During the dispensing, handling, administration, and disposal of pharmaceuticals, this exposure to such substances may occur.

If these specialists don't take any measures, handling these medications on a daily basis could lead to health problems. Healthcare professionals shouldn't allow cytotoxic medications to be exposed to the environment in order to protect themselves from their adverse effects. When these cytotoxic medications are exposed to the environment and come into contact with healthcare professionals by inhalation, ingestion, or cutaneous contact, the aforementioned problems occur.

Therefore, preventing these medications from being exposed to the environment is the most likely answer to all of these problems. And in order to prevent this exposure, either extra care must be used when handling, or specific commercially accessible medical devices might be employed.

INTRODUCTION

What are cytotoxic drugs?

These are the drugs that are given to the body as part of chemotherapy to treat cancer cells. These medications work by influencing the cell division-related structures to inhibit the unchecked proliferation of bodily cells.

These medications have mutagenic and carcinogenic properties, which are extremely detrimental to the body's natural cells.

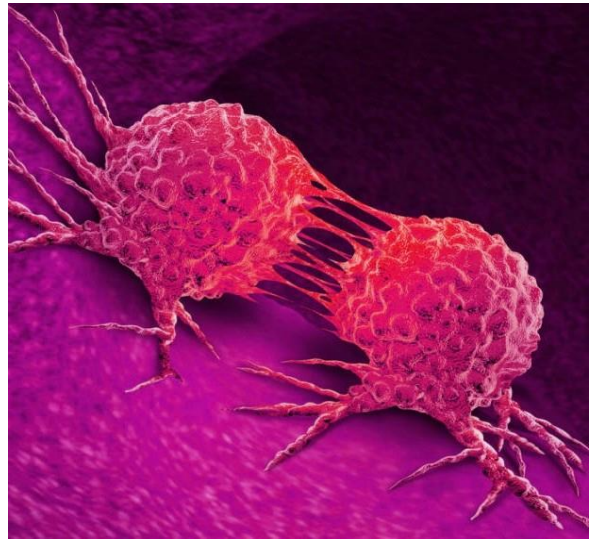
CANCER

Cancer is a disease in which DNA damage or genetic abnormalities cause uncontrolled cell proliferation. The ability of a normal cell to stop dividing when it comes into contact with another cell during division is known as contact inhibition. Cancer cells lack this ability due to genetic mutation, which can be caused by a variety of stimuli including radiation, toxins, tiny particulate matter, etc. Carcinogens are substances that cause cancer.

In the condition of cancer when uncontrolled cell growth occurs of any tissue it is called as tumor and these tumors are of two types benign and malignant.

Because benign does not spread, whereas malignant grows and spreads into other parts of the body, the latter is lethal. This process is known as metastasis.

There are a variety of ways to diagnose cancer, but the most reliable method is to examine a biopsy sample of the suspected tissue. This biopsy test determines the stage of the disease, its severity, and how far it has spread throughout the body. The treatment plan then begins in accordance with this information. Numerous methods, such as surgery, chemotherapy, and radiation therapy, are used in the treatment of cancer.



Types of cancer

- A. **Carcinoma** - It is a type of cancer that starts in the skin or the tissue that covers or lines the other organs.
- B. **Sarcoma** - It is the cancer of connective tissues like muscles, cartilage, bones, etc.

C. **Leukaemia** - It is a cancer of bone marrow.

D. **Lymphoma** - It is a cancer of immune system.

Despite the fact that chemotherapy is one of the most well-known cancer treatments, alternative treatments include surgery, radiation, bone marrow transplants, immunotherapy, and targeted medication therapy. Cytotoxic medicines, which are toxic to cells, are employed in chemotherapy to kill cancer cells.

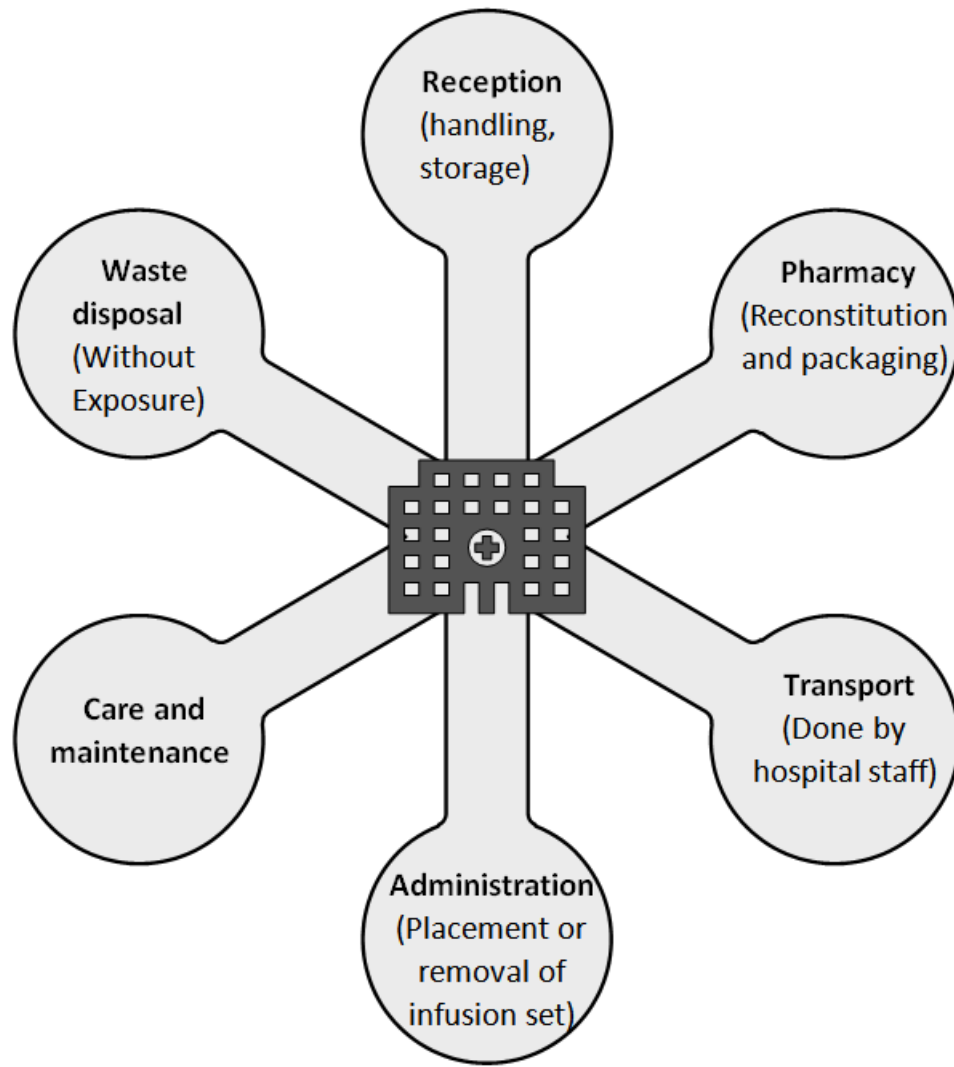
In addition, these cytotoxic medications are extremely dangerous to healthy individuals. Therefore, it is imperative to practise caution and safety when dispensing, administering, handling, and disposing of these medications.

Patients are regularly exposed to these medications in an oncology department where medical professionals strive to treat cancer. And as a result of their exposure with these drugs, medical personnel are at risk for getting conditions like skin and throat irritations, allergic reactions, headaches, hair loss, nausea, vomiting, and diarrhoea, birth malformations, infertility, and in some cases, cancer.

❖ Who are involved in chemotherapy process ?

- **Oncologist** - Receive the patient analyse blood and prescribe chemotherapy.
- **Nurse** - Administer the medication into the patient.
- **Pharmacist** - Make sure the availability of the prescribed medication for chemotherapy.
- **Laboratory technician** - Prepare the drugs.

❖ Chemotherapy process in a hospital



There are mainly three times when the chances of exposure of drugs are more :

1. **Preparation** - At the time of preparation of medication in the pharmacy.
2. **Administration** - When treatment is being delivered to the patient.
3. **Disposal** - At the time of disposal of used infusion set.

Mechanism of contamination

When cytotoxic drugs exposed in the environment there are mainly three ways by which drug can enter in the body to show its negative effects:



A. Cutaneous contacts



B. Inhalation



C. Ingestion

Consequences

- Skin irritation, throat irritation
- Allergic reactions, Hairloss
- Headaches, Nausea, Vomiting and Diarrhoea
- Congenital defects
- Increased risk of spontaneous abortions
- Infertility
- Increased risk of developing a cancer.

The effects of exposure to these cytotoxic medications on healthcare workers have been demonstrated in numerous studies to range from a minor hair loss issue to a more serious miscarriage issue, making it imperative to take measures when handling these drugs. And in this study, we'll find out how prevalent these problems are among healthcare professionals in India and what steps hospital administration is taking to protect its employees from them.

OBJECTIVES

- ❖ To study the effects of chemotherapy on healthcare practitioners. (Q.3, Q.4,Q.5)
- ❖ To observe and understand their awareness and precautions taken during chemotherapy. (Q.6, Q.7)
- ❖ To learn and understand the approach used by healthcare practitioners in oncology department during chemotherapy. (Q.8, Q.9, Q.10)

LITERATURE REVIEW

OCCUPATIONAL EXPOSURE TO PLATINUM DRUGS DURING INTRAPERITONEAL CHEMOTHERAPY BIOMONITORING AND SURFACE CONTAMINATION

S Ndaw, O Hanser, V Kenepekian, M Vidal, M Melczer, ARemy, A Robert, N Bakrin (2018)

HIPEC (Hyper-thermic intraperitoneal chemotherapy) is treatment method used over last decade for the treatment of peritoneal carcinomatosis. The chemotherapy drug is heated and injected into the abdominal cavity during this treatment, assuring exposure to cancer cells while minimising systemic damage.

A further useful technique is PIPAC, or pressurised intraperitoneal aerosol chemotherapy, in which a chemotherapy medication is administered under pressure in the form of an aerosol into the peritoneal cavity. As a novel approach, this treatment is especially recommended for patients receiving palliative care.

The advantage of PIPAC over HIPEC is that 10 times less chemotherapeutic agent is used in the former approach than in the latter.

The surgical staff runs a risk while using antineoplastic drugs in any of the aforementioned approaches. This study focuses on the possible risk posed to the medical staff during PIPAC and HIPEC procedures by surface contamination measures and biomonitoring methods.

Method : Urine samples were collected from 10 volunteers and a control group of medical care givers. The operation room and its staff provided wipe samples of their hands, gloves, floors, and equipment. Inductively coupled plasma mass spectroscopy was utilised to analyse platinum.

Result : About 50% of the urinary samples showed platinum content below the limit of quantification (less than 10 ng/L). While considerable contamination was seen in the wipe samples taken from operating room staff who were performing PIPAC and HIPEC as well as from samples taken from gloves, hands, the operating room floor, and gadgets. The concentrations did not differ considerably in the case of the control group.

A STUDY OF OCCUPATIONAL EXPOSURE TO ANTINEOPLASTIC DRUGS AND FETAL LOSS IN NURSES

Sherry G. Selevan, Ph. D., Marja-Liisa Lindbohm, CandPolSci, Richard W. Hornung, Dr. Ph., and Kari Hemminki, M.D. (1985)

This study was done in 17 Finnish hospitals where through case-control study, the relationship between anti neoplastic drugs and fetal losses in nurses has been examined. The pregnancies that were studied in this research occurred in 1973 through 1980.

These cases were identified using three sources :

- The polyclinical data
- The hospital discharge registry
- The central register of health care personnel

Three more nurses who had given birth were matched with all the other nurses.

a strong link exists between first-trimester foetal loss and anti-neoplastic medication exposure. Since the majority of the nurses were handling many anti-neoplastic medications, such as doxorubicin, vincristine, cyclophosphamide, etc. As a result, the independent impact of these medications on the growing foetus could not be determined.

This study primarily focuses on offering safety precautions for using these anti-neoplastic medicines based on its findings in conjunction with data from pre-clinical and clinical testing.

HANDLING ANTINEOPLASTIC AGENTS : URINE MUTAGENICITY IN NURSES

Bonnie Rogers, Edward A. Emmett (1987)

Many studies have suggested that handling antineoplastic agents are associated with potential health hazards.

For this study urine samples and interviews were collected from 64 non exposed and 59 exposed nurses. The assay were compared from exposed and non exposed nurses (3 to 5 working days with one non exposure day).

Through interviews, information about a person's work history, past pregnancies, demographics, medications, smoking habits, use of protective measures, and kind, frequency, and length of anti-neoplastic drug exposure was gathered.

The findings of the study were :

- Nurses who were exposed to antineoplastic agents (depending on frequency and duration) were more likely to have urine mutagenicity comparing to thenon-exposed nurses.
- The nurses who were working at private clinics and private oncology practices were at greater risk.

- A significant proportion of pregnancy complication occurred in exposed nurses as compared to nurses who were not exposed to anti-neoplastic agents in their workplace.

MONITORING OF OXIDATIVE STRESS IN NURSES OCCUPATIONALLY EXPOSED TO ANTINEOPLASTIC DRUGS

M. Mahboob, M. F. Rahman, P. V. Rekhadevi, N. Sailaja, A. Balasubramanyam, P.V. Prabhakar, Shailendra Pratap Singh, Utkarsh A. Reddy, G. Sankara Rao and Paramjit Grover (2019)

Antineoplastic agents, or ANDs, have been used in clinical practice for at least 50 years, but because of the non-selective mechanism of action of these drugs on both cancerous and healthy cells, they can cause adverse reactions, cytotoxic effects, and reproductive issues in people who work in healthcare.

There are more than 50 identified ANDs, and the majority of them are mutagenic, carcinogenic, or teratogenic. When administering medications to patients, cleaning up spills, or dealing with patients' emesis, excrement, sweat, urine, or contaminated clothing or linen, nurses are exposed to these dangerous chemicals. The majority of hospitals take care to reduce exposure through proper education and safety procedures, however despite these efforts, medications have been discovered in urine samples taken from exposed nurses.

The side effects that have been observed in nurses who have been exposed to anti-neoplastic drugs at work range from acute symptoms like nausea, diarrhoea, vomiting, headache, mucosa irritation (skin, eyes, and throat), hair loss, headache, and dizziness to chronic effects like menstrual irregularities, cancer, miscarriages, genotoxicity, and foetal malformation.

Reactive oxygen species (ROS), which are also to blame for the many adverse effects of chemotherapy in patients as well as healthcare professionals exposed to them, are the principal mechanism of action of these ANDs. ROS are produced as a result of the production of free radicals. The lipids, proteins, and nucleic acids are damaged by these ROS, which causes oxidative stress.

In this study, nurses' oxidative stress from antineoplastic drugs is compared to that of non-exposed nurses. Serum from 60 nurses who regularly handle ANDs is analysed for malondialdehyde levels, glutathione content, and glutathione S-transferase activity for this reason.

This study includes nurses who have had a minimum of 5 year experience of working in an oncology department for at least 5 days a week.

Result : A significant increase in malondialdehyde level in the serum of exposed nurses is noticed.

The level of glutathione and glutathione S-transferase activity was significantly decreased in exposed nurses.

Conclusion : A standardised set of safe handling procedures and guidelines are urgently needed because nurses frequently exposed to ANDs at work are prone to oxidative damage..

RESEARCH METHODOLOGY AND PRESENTATION OF THE DATA

TYPE OF RESEARCH

Research is the systematic collection and analysis of data for the purpose of achieving research goals using a design strategy that best supports those goals. The research methodology and sample techniques are chosen based on the research design.

There are two types of research designs:

- 1. Exploratory research**
- 2. Descriptive research**

Exploratory research :

The goal is to examine, research, and plan for a more focused investigation, as the name suggests. The primary goal is to learn more about the thoughts and ideas, and the structure is ad hoc. The design is adaptable and focuses on clarifying a murky issue in order to get a clearer picture for a thorough inquiry. The creation of hypotheses to explain any phenomenon is aided by this type of study strategy.

Descriptive research :

This kind of study is more organised and outlines the features and functions. Descriptive research collects statistical data that is used to determine the solution to the study problem and is more pictorial in nature.

While descriptive research provides the final judgement, exploratory research provides a picture of what, why, where, when, who, and how. Simply put, descriptive research fills in the gaps left by exploratory research.

Both an exploratory and a descriptive research strategy were used for this investigation.

TOOLS USED FOR DATA COLLECTION

Sample Size- 66 HCP's including oncologists, resident doctors, nurses, and lab technicians.

Sampling Method : Questionnaire consisting of 10 structured question

Questionnaire design

A set of twelve questions is used to collect data for the objectives of the research.

The framework of this study, which consists of the variables and research questions, is based on the literature review. The goals are established to support the research problem. The conclusion is drawn using data gathered for a questionnaire that contains many questions relating to the variables under research. The variables are mapped based on a literature review.

Sources of Data

For this study data is collected from primary as well as secondary sources.

Primary Source

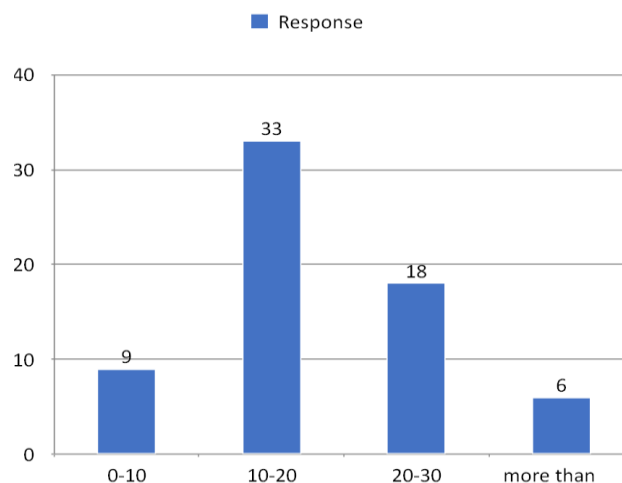
Primary information was gathered through questionnaires and individual interviews. With the aid of interview notes and direct communication, the healthcare professional provided more qualitative insight.

Secondary sources

Secondary data are those gathered from previously published studies. Literature books, articles, and research papers were employed as sources for this study.

Result and Analysis

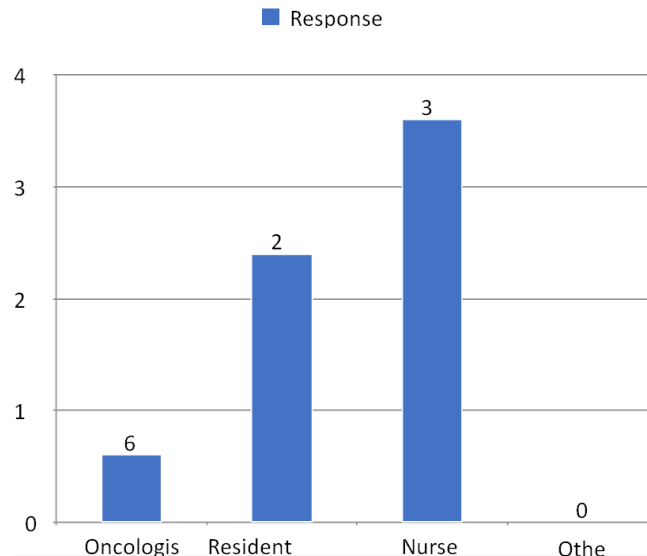
How many chemotherapy sessions are usually done in your hospital in a month?



- **Result & Interpretation-** 33 out of 66 healthcare practitioners told that around 10 to 20 chemotherapy sessions are usually done in a month in their hospital. 18 said 20 to 30 are usually done, 9 said 0 to 10 sessions has done only 6 has told that more

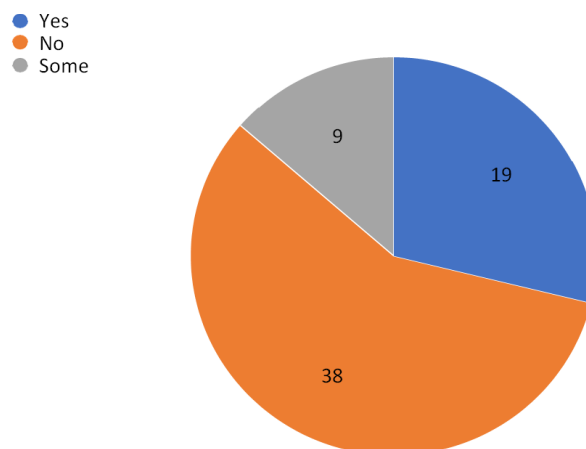
than 30 chemotherapy sessions has been done in their hospital in a month. This data shows that normally in a hospital 10 to 20 chemotherapy sessions are usually done.

Who handles the responsibility of drug administration in patient for chemotherapy?



- **Result & Interpretation** - 36 nurses out of 66 healthcare practitioners handled the responsibility of drug administration where 24 resident doctors handle this responsibility and in 6 cases oncologists handle this responsibility but no other staff allowed to perform this activity. This Shows that mainly nursing staff and resident doctors are at the high risk of getting exposure and harmful effects of cytotoxic drugs.

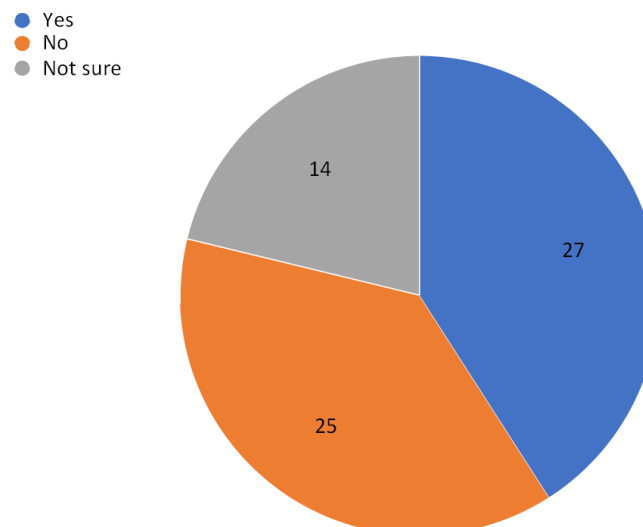
Are you aware of the harmful effects of cytotoxic drugs that are being used in chemotherapy to the healthcare providers?



- **Result & Interpretation** - 38 out of 66 healthcare practitioners are not aware about the harmful effects of cytotoxic drugs in which all of the HCP's are nursing and other staff and 19

out of 66 healthcare practitioners know about the harmful effects of these drugs and these all 19 HCP's are either oncologists or senior nursing staff. Rest of 9 out of 66 are not fully aware about the effects of cytotoxic drugs on the health. This shows that only oncologists and senior nursing staff are aware of the harmful effects of the cytotoxic drugs but junior nursing staff as well as other technicians lack this knowledge and so they are at the high-risk. So they need to get the knowledge about the handling of these cytotoxic drugs and what harm they can do to their body.

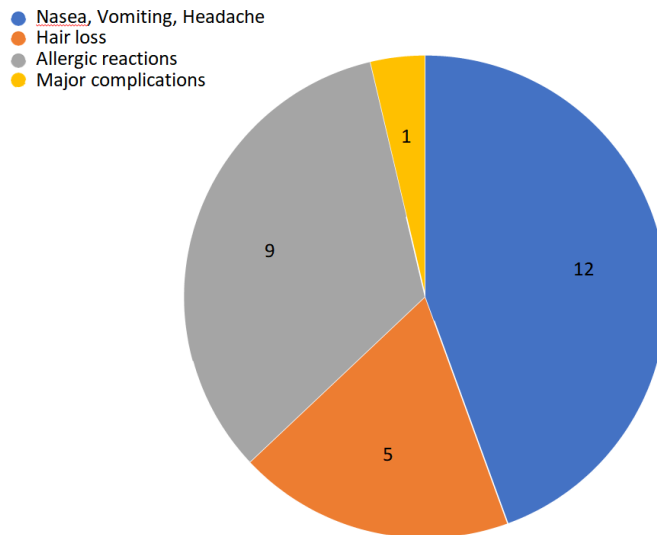
Have you faced any kind of such issues related to these drugs before?



- **Result & Interpretation** - 27 out of 66 HCP's have faced some issues on their health related to these drugs, 25 never have faced any issues on their health and 14 were not sure about the impact of these drugs on their health.

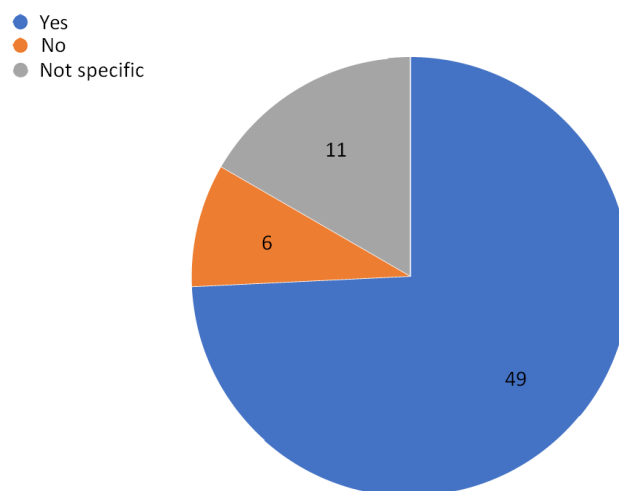
What issues have you faced?

Out of 27 who answered yes in previous question.



- **Result & Interpretation** - 12 Out of 27 HCP's Who answered yes in previous question said that they have faced some common issues like nausea,vomiting, headache sometimes after getting exposure of these drugs. 5 said that they have faced problem of hair loss after entering in this profession, 9 said that they have experienced some sort of allergic reactions after getting contact of these drugs allergies like skin problems, throat irritations etc. And in all these 27 HCP's only one case found where a nurse said that she had a miscarriage in past but she is not sure that is it because of this exposure of cytotoxic drugs or any other problem.

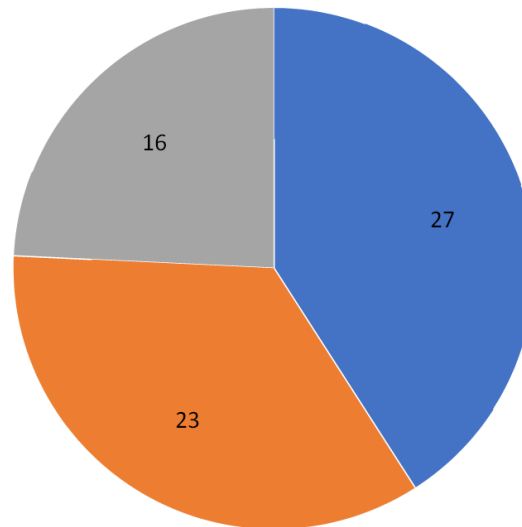
Do you have any guidelines related to cytotoxic drug handling in yourhospital?



Result & Interpretation - 49 out of 66 healthcare practitioners said that they have guidelines related to handling of cytotoxic drugs, 6 said that they don't have any guidelines related to cytotoxic drugs and 11 said that they don't have specific guidelines related to cytotoxic drugs. This shows that maximum number of hospitals have their own guidelines on handling cytotoxic drugs carefully.

Do you consider that every time when you start giving the medication to the patient exposure of drug occurs in the environment?

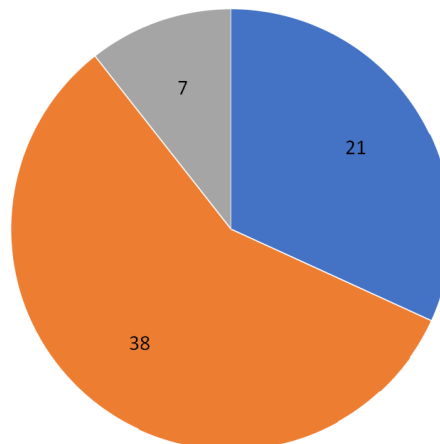
● Yes
● No
● Sometimes



- **Result & Interpretation** - 27 out of 66 HCP's said that maximum time when they start giving medication or remove the infusion set exposure of few drops of cytotoxic drug occurs commonly while 23 said that they do their work with full safety and precaution and do not let these drugs expose to the environment and 16 said that it happens sometimes not always.

Are you aware about the closed system transfer devices available in the market which prevent the exposure of such drugs to the environment?

● Yes
● No
● Maybe



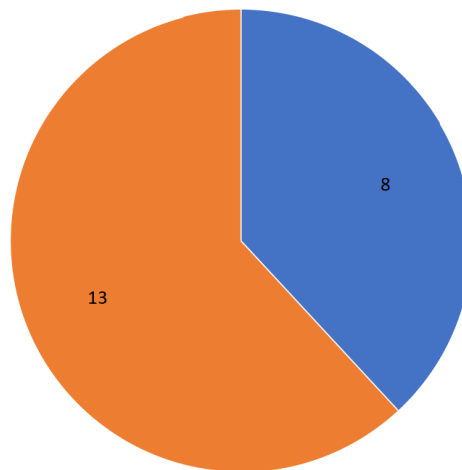
Result & Interpretation - 38 out of 66 healthcare practitioners said that they are not aware about the closed system transfer devices available in the market majority of them are the nursing and other staff, 21 were aware about the closed system transfer devices and seven were not sure about these devices. This shows that majority of healthcare

practitioners are not aware about these devices available in the market to prevent the exposure of cytotoxic drugs to the environment which ultimately protect them from the bad effects of such drugs.

Are you currently using any CSTD devices ?

Out of 21 aware HCP's

● Yes
● No

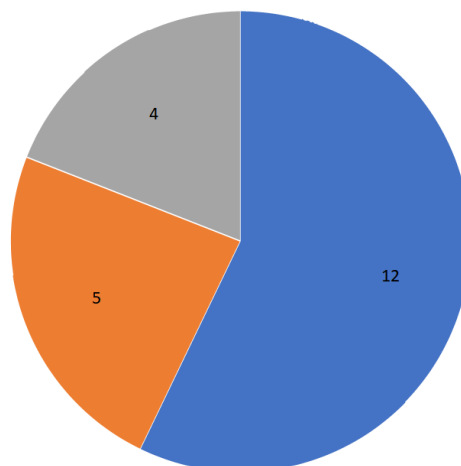


- **Result & Interpretation** - only 13 out of aware healthcare practitioners currently using CSTD devices and rest eight were not using because they prefer safety and precaution over these devices.

- ❖ Do you think that CSTD devices prevent the exposure of the cytotoxic drugs to the environment and thus minimises the health related hazards to the HCP's ?

Out of 21 aware HCP's.

● Yes
● No
● Not sure



- **Result & Interpretation** - 12 out of 21 aware HCP's think that CSTD devices prevent the exposure of cytotoxic drugs to the environment 5 do not consider this fact and four are not sure about this. This shows that most of the HCP's who are using CSTD devices are convinced that using these devices they can prevent the exposure of cytotoxic drugs to the environment and prevent themselves from their harmful effect.

Conclusion

It is evident from the comments of medical professionals that cytotoxic medications have many detrimental consequences on the health of normal human bodies. The most typical health symptoms include headaches, allergic reactions, nausea, and vomiting. Although there may be other, higher dangers, HCPs are most likely to encounter these.

The majority of healthcare professionals, including nursing staff and other staff, are not aware of the negative effects of the cytotoxic drugs they are handling to provide chemotherapy, but oncologists and senior nursing staff are. This observation relates to their awareness and precautions taken during chemotherapy. Additionally, they have specific instructions on how to handle and dispose of the drugs in order to prevent exposure to these deadly substances.

When it comes to the method used by HCPs to prevent the release of these cytotoxic drugs into the environment and to lessen their side effects, they either take safety measures and precautions when handling the drugs or, in some cases, use close-system medical devices. Only a small percentage of healthcare professionals use this method, but it is an effective one. More than 50% of HCPs who use such devices are happy with the outcomes, although some of them think that only by exercising prudence and safety measures can they completely eliminate any negative effects by preventing the pharmaceuticals from being exposed to the environment..

QUESTIONNAIRE

Q-1) How many chemotherapy sessions are usually done in your hospital in a month ?

- A. 0-10
- B. 10-20
- C. 20-30
- D. More than 30

Q-2) Who handles the responsibility of drug administration in patient for chemotherapy ?

- A. Oncologist

B. Resident doctors

C. Nurses

D. Other medical staff

Q-3) Are you aware of the harmful effects of cytotoxic drugs that are being used in chemotherapy to the healthcare providers ?

A. Yes

B. No

C. Some

Q-4) Have you faced any kind of such issues related to these drugs before ?

A. Yes

B. No

C. Not sure

Q-5) What issues have you faced ?

A. Nausea, Vomiting, Headache

B. Hair loss

C. Allergic reactions on skin or throat

D. Major complications like miscarriage, infertility, cancer etc

Q-6) Do you have any guidelines related to cytotoxic drug handling in your hospital ?

A. Yes

B. No

C. No specific guidelines

Q-7) Do you consider that every time when you start giving the medication to the patient exposure of drug occurs in the environment?

A. Yes

B. No

C. Sometimes

Q-8) Are you aware about the closed system transfer devices available in the market which prevent the exposure of such drugs to the environment ?

A. Yes

B. No

C. May be

Q-9) Are you currently using any CSTD devices ?

A. Yes

B. No

Q-10) Do you think that CSTD devices prevent the exposure of the cytotoxic drugs to the environment and thus minimises the health related hazards to the HCP's ?

A. Yes

B. No

C. Not sure

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