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A SELF STUDY GUIDE

CHEMOTHERAPY AND MEDICAL GLOVES

Registered Nurses

CHEMOTHERAPY AND MEDICAL GLOVES

OVERVIEW

Cancer treatment involves medical procedures to destroy, modify, control, or remove primary, regional, or metastatic cancer tissue. The goals of cancer treatment include eradicating known tumors entirely, preventing the recurrence or spread of the primary cancer, and relieving symptoms if all reasonable curative approaches have been exhausted. Decisions concerning how to treat a particular cancer are based on many factors, with the primary goal to choose an approach that will remove the tumor, the wandering cancer cells, and prevent a recurrence. Any treatment that is given to modify, control, remove or destroy primary or metastatic cancer tissue is cancer-directed treatment. This learning module provides a brief discussion on common cancer treatment approaches and detailed information pertaining to chemotherapy and personal protective equipment.

LEARNER OBJECTIVES

Upon completion of this continuing education activity, the participant should be able to:

1. Describe the goal of cancer treatment.
2. Name the various treatment procedures for cancer and the benefit of each option.
3. Identify the types of chemotherapy drugs used.
4. Identify how gloves are tested and approved for use with chemotherapy agents.
5. Describe the appropriate gloves for chemotherapy.

INTENDED AUDIENCE

The information contained in this self-study guidebook is intended for use by healthcare professionals who are responsible for or involved in the following activities related to this topic:

- Educating healthcare personnel
- Establishing institutional or departmental policies and procedures
- Decision-making responsibilities for safety and infection prevention products
- Maintaining regulatory compliance
- Managing employee health and infection prevention services

INSTRUCTIONS

Ansell Healthcare is a provider approved by the California Board of Registered Nursing, Provider # CEP 15538 and the Australian College of Perioperative Nurses (ACORN). This course has been accredited for 2 (two) contact hours. Obtaining full credit for this offering depends on completion of the self-study materials on-line as directed below.

Approval refers to recognition of educational activities only and does not imply endorsement of any product or company displayed in any form during the educational activity.

To receive contact hours for this program, please go to the "Program Tests" area and complete the post-test. You will receive your certificate via email.

AN 85% PASSING SCORE IS REQUIRED FOR SUCCESSFUL COMPLETION. Any learner who does not successfully complete the post-test will be notified and given an opportunity to resubmit for certification.

For more information about our educational programs or perioperative safety solution topics, please contact Ansell Healthcare Educational Services by e-mail at edu@ansellhealthcare.com.

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As employees of Ansell Ms. Ouellet, Mrs. Richardson, Mrs. Taylor and Ms. Werner have declared an affiliation that could be perceived as posing a potential conflict of interest with development of this self-study module.

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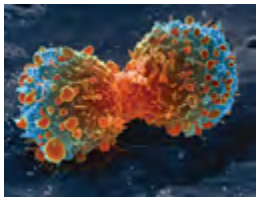
INTRODUCTION TO CANCER

Cancer is the name given to a collection of related diseases. In all types of cancer, some of the body's cells begin to continuously divide and spread into surrounding tissues. Cancer can start almost anywhere in the human body, which is made up of trillions of cells. As cells become more and more abnormal, old or damaged cells survive when they should die, and new cells form when they are not needed. In addition, as these tumors grow, some cancer cells can break off and travel to distant places in the body through the blood or the lymph system and form new tumors far from the original tumor.

DIFFERENCES BETWEEN CANCER CELLS AND NORMAL CELLS [1, 2]

Cancer cells differ from normal cells in many ways that allow them to grow out of control and become invasive. One important difference is that cancer cells are less specialized than normal cells. That is, whereas normal cells mature into very distinct cell types with specific functions, cancer cells do not. This is one reason cancer cells, unlike normal cells, continue to divide without stopping. Cancer cells can induce nearby normal cells to form blood vessels that supply tumors with oxygen and nutrients, which they need to grow. Cancer cells are also often able to evade the immune system, a network of organs, tissues, and specialized cells that protects the body from infections.



Lung cancer cells during cell division. Source: NIH

HOW CANCER OCCURS [3]

Cancer is a genetic disease caused by changes to genes that control the way our cells function, especially how they grow and divide. In general, cancer cells have more genetic changes, such as mutations in DNA, than normal cells. Cancer arises from the transformation of normal cells into tumor cells in a multistage process that generally progresses from a pre-cancerous lesion to a malignant tumor. These changes are the result of the interaction between a person's genetic factors and 3 categories of external agents, including:

- physical carcinogens, such as ultraviolet and ionizing radiation;
- chemical carcinogens, such as asbestos, components of tobacco smoke, aflatoxin (a food contaminant), and arsenic (a drinking water contaminant); and
- biological carcinogens, such as infections from certain viruses, bacteria, or parasites.

INCIDENCE OF CANCER [4,5]

According to the World Health Organization (WHO) February 2017 Cancer Fact Sheet, cancer is a leading cause of death worldwide, accounting for 8.8 million deaths in 2015. The most common causes of cancer death are cancers of:

- Lung (1.69 million deaths)
- Liver (788 000 deaths)
- Colorectal (774 000 deaths)
- Stomach (754 000 deaths)
- Breast (571 000 deaths)

Further, the WHO notes that the economic impact of cancer is significant and is increasing. The total annual economic cost of cancer in 2010 was estimated at approximately US$1.16 trillion.

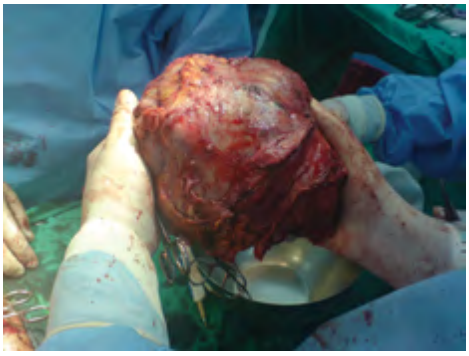
Cancer statistics from other countries reveal the following:

- In 2016, an estimated 1,685,210 new cases of cancer will be diagnosed in the United States and 595,690 people will die from the disease. [6]
- An estimated 3.5 million new cancer cases and 1.9 million cancer deaths occurred in Europe in 2012. [7]
- In 2013, there were 124,465 new cases of cancer diagnosed in Australia (68,936 males and 55,529 females). In 2017, it is estimated that 134,174 new cases of cancer will be diagnosed in Australia (72,169 males and 62,005 females). [8]
- Asia, with 56% of the world's population (3.8 billion), contributes 44% of all cancer cases (6.4 million out of 14.1 million) and 51% of all cancer deaths (4.3 million out of 8.2 million) globally, with China representing much of the cancer burden. [9]

CANCER TREATMENT PROCEDURES [10]

SURGERY

Cancer surgery attempts to completely remove localized tumors or reduce the size of large tumors so that follow-up treatment by radiation or chemotherapy will be more effective. Generally, surgery involves cutting into the body (incision) to explore or remove tissue while the patient is under anesthesia. Surgical techniques used for surgery include cryosurgery, electro cauterization surgery, laser surgery, gamma knife, and en bloc resection.



Surgical removal of large liver tumor.

RADIATION THERAPY

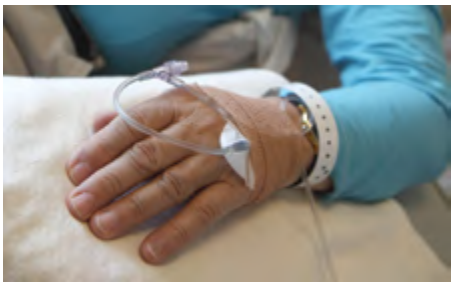
Radiation therapy uses x-rays, gamma rays and other sources of radiation to destroy cancer cells. Radiation kills cells by breaking up molecules and causing reactions that damage living cells. Sometimes the cells are destroyed immediately; sometimes certain components of cells, such as their deoxyribonucleic acid (DNA), are damaged, thereby affecting the ability of the cell to divide. Radiation therapy is often used in combination with chemotherapy agents.

Radiation Therapy Source: National Cancer Institute (NCI)

CHEMOTHERAPY AND MEDICAL GLOVES

CHEMOTHERAPY

Chemotherapy is the treatment of cancer with chemical agents. Chemotherapy is a distinctively different approach than surgery and radiation therapy to treat cancer. Rather than physically removing a tumor or a part of it, chemotherapy uses chemical agents (anti-cancer or cytotoxic drugs) to interact with cancer cells to eradicate or control the growth of cancer. We will discuss this in further detail in this education module.



HORMONE THERAPY

Rarely given as a single agent to attempt to cure cancer, hormones are often used to prevent or delay recurrence of cancer after other modalities of treatment have removed the gross primary tumor and chemotherapy or radiation therapy have treated systemic and regional micro-metastases.

BIOLOGICAL THERAPY

There are two basic categories of biological therapy: immunotherapy and cytotoxic therapy. Immunotherapy uses a variety of methods and drugs to manipulate the immune system. This creates a hostile environment for the existence or growth of cancer in the body.

INTRODUCTION TO CHEMOTHERAPY [11,12]

Chemotherapy (also called Chemo) is a type of cancer treatment that uses drugs to destroy cells. Rather than physically removing a tumor or a part of it, chemotherapy uses chemical agents (anti-cancer or cytotoxic drugs) to interact with cancer cells to eradicate or control the growth of cancer.

Chemotherapy as a cancer treatment can be traced back to the ancient Egyptians, who used compounds of barley, pigs' ears, and other ingredients to treat cancers of the stomach and the uterus. Paul Ehrlich originated the term chemotherapy in 1914 while searching for a substance to cure syphilis. During World War I, it was found that soldiers who were exposed to sulfur mustard suffered from lower white blood cell counts. This discovery led to the use of nitrogen mustard, a similar but less toxic chemical agent, to cure patients with high white blood cells counts (lymphoid leukemia) and lymphomas. Later, more chemical substances were studied and tested, becoming chemotherapeutical drugs for cancer treatment.

UNDERSTANDING THE LIFE CYCLE OF A CELL [13,14]

All living tissue is made up of cells. Cells grow and reproduce to replace cells lost through injury or normal "wear and tear." The cell cycle is the normal life cycle of a cell. It's a series of steps that both normal cells and cancer cells go through to form new cells. Understanding the cell cycle helps doctors predict which drugs are likely to work well together and decide how often doses of each drug should be given. Cells divide by going through a cell cycle, following an ordered set of events that include the synthesis of DNA (S-phase), mitosis (M-phase), culminating in cell growth and division into two daughter cells. Normal cells grow and die in a precisely controlled way while cancer occurs when the process becomes abnormal, with cells dividing and forming more cells without control and order.

PHASES OF THE CELL CYCLE

The cell cycle has 5 phases. Since cell reproduction happens over and over, the cell cycle is shown as a circle. All the phases lead back to the resting phase (G0), which is the starting point. When a cell goes through the cell cycle, it reproduces 2 new identical cells. Each of the 2 cells made from the first cell can go through this cell cycle again when new cells are needed.

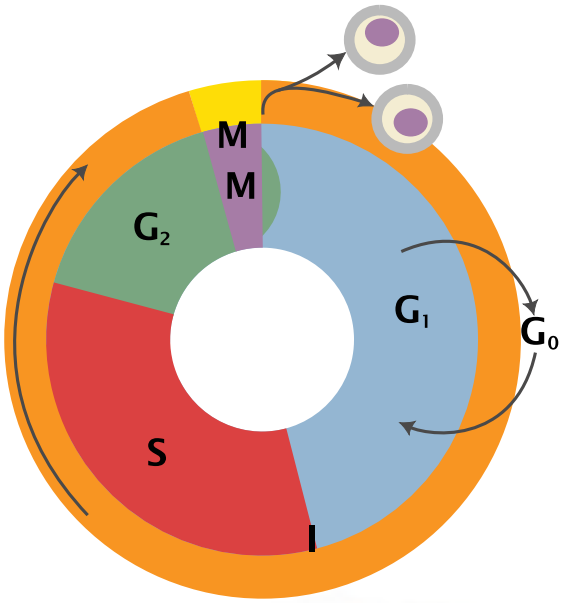
Gap 0 (G0) phase (resting stage)
The cell has not yet started to divide. Cells spend much of their lives in this phase. Depending on the type of cell, G0 can last from a few hours to a few years. When the cell gets a signal to reproduce, it moves into the G1 phase.

Gap 1 (G1) phase
The cell starts making more proteins and growing larger, so the new cells will be of normal size. This phase lasts about 18 to 30 hours.

Synthesis (S) phase
The chromosomes containing the genetic code (DNA) are copied so that both new cells formed will have matching strands of DNA. This phase lasts about 18 to 20 hours.

Gap 2 (G2) phase
The cell checks the DNA and gets ready to start splitting into 2 cells. This phase lasts from 2 to 10 hours.

Mitosis (M) phase
The cell splits into 2 new cells. This phase lasts only 30 to 60 minutes.



Schematic representation of the cell cycle.
By Richard Wheeler (Zephyris) 2006.

WHY THE CELL CYCLE MATTERS

The cell cycle is important because many chemotherapy drugs work only on cells that are actively reproducing (not cells that are in the resting phase, G0). Some drugs specially attack cells in a particular phase of the cell cycle (the M or S phases, for example). Doctors can prescribe the type of chemotherapy and the dose of the chemotherapy based upon the timing of cell phases.

Since chemotherapy cannot distinguish the difference between normal cells and cancer cells, both types of cells are affected by chemotherapy. Fortunately, normal cells are able to repair themselves.

CHEMOTHERAPY AND MEDICAL GLOVES

CHEMOTHERAPY [15, 16, 17]

Chemotherapy is a systemic method of cancer treatment, in contrast with local therapies such as surgery and radiation therapy. The drugs used in chemotherapy can reach most parts of the body. Therefore, chemotherapy is likely to be recommended for cancer that has already spread to other areas of the body, for tumors that occur at more than one site, or for tumors that cannot be removed surgically. It is also used when a patient has recurrent disease after initial treatment with surgery or radiation therapy. Chemotherapy is less mutilating than surgery and helps conserve organ or limb function since anti-cancer drugs are used to act on cancer cells without direct removal of a body part.

For some cancers, chemotherapy alone can destroy all the cancer cells and cure the cancer (primary treatment). As an adjuvant treatment, chemotherapy is given prior to, or after other methods, to increase the effectiveness of cancer treatment. Most often, adjuvant chemotherapy is given after other therapies have destroyed the clinically detectable cancer cells. The purpose of adjuvant chemotherapy is to reduce the risk of recurrence or to prolong survival. If cure is not possible, chemotherapy may be given to minimize the discomfort caused by cancer or slow the progression of the disease to prolong the patient's life (palliative treatment). Chemotherapy may be given prior to surgical resection or radiation therapy to shrink the tumor and make it easier to resect. This type of chemotherapy is called neoadjuvant, induction, or preoperative chemotherapy. As a palliative therapy, chemotherapy can be used to help make the cancer patient's life as comfortable as possible.

Every cancer is unique, as is every cancer patient; therefore, the oncologist takes great care to tailor the chemotherapy plan to the particular case. The treatment protocol specifies what type of drug(s) should be given, what dosage should be given, how to administer the drug(s), how often the drug(s) should be given, and how long the treatment should last. During chemotherapy, the oncologist, who may change or modify the treatment plan to achieve better results, closely monitors the progress of the cancer patient and the tumor response. [18]

TYPES OF CHEMOTHERAPY DRUGS [19]

Chemotherapy drugs can be divided into serval groups/classes based upon based upon factors such as how they work, their chemical structure and their relationship to other drugs. More than 100 chemotherapy drugs are used today – either alone or in combination with other drugs.

Drugs in the same class kill cancer cells by the same mechanism: they all attack the same target within the cell. Depending on the type of cancer and the kind of drug used, chemotherapy drugs may be administered differently. They can be administered orally (oral chemotherapy), or injected into a muscle (intramuscular injection), injected under the skin (subcutaneous injection), or into a vein (intravenous chemotherapy). In special cases, chemotherapy drugs may be injected into the fluid around the spine (intrathecal chemotherapy). Two or more methods of administration may be used at the same time under certain circumstances. No matter what method is used, chemotherapy drugs are absorbed into the blood and carried around the body. Of all the methods of chemotherapy drug administration mentioned above, intravenous injection is most commonly used. It is the most efficient way to get the medication into the bloodstream. Oral chemotherapy is more convenient and does not require any specialized equipment. Since different chemical agents damage cancer cells in different ways and at different phases in the cell cycle, a combination of drugs is often employed to increase the cancerous cell-killing effectiveness. This is called combination chemotherapy (often referred to as a chemo cocktail).

Listed are several major categories (classes) of chemotherapy agents based on their chemical structures and their mechanism of action (the way they act) on cancer cells. According to the National Institute of Health/National Cancer Institute, classifying drugs according to their mechanism of action is the preferred system in use between clinicians. Although you may find chemotherapy drugs classified differently, in this training module we will classify chemotherapy drugs based upon their chemical structure.

Alkylating agents

Alkylating agents are the most commonly used agents in chemotherapy today. Alkylating agents act directly on DNA, causing cross-linking of DNA strands, abnormal base pairing, or DNA strand breaks, thus preventing the cell from dividing. Alkylating agents are generally considered to be cell cycle phase nonspecific, meaning that they kill the cell in various and multiple phases of the cell cycle. They are generally of greatest value in treating slow-growing cancers.

Antimetabolites

Antimetabolites replace natural substances as building blocks in DNA molecules, thereby altering the function of enzymes required for cell metabolism and protein synthesis. In other words, they mimic nutrients that the cell needs to grow, tricking the cell into consuming them, so it eventually starves to death. Antimetabolites are cell cycle specific and most effective during the S-phase of cell division because they primarily act upon cells undergoing synthesis of new DNA for formation of new cells. The toxicities associated with these drugs are seen in cells that are growing and dividing quickly.

Plant alkaloids

Plant alkaloids, often referred to as spindle poisons or natural products, are antitumor agents derived from plants. These drugs act specifically by blocking the ability of a cancer cell to divide and become two cells. Although they act throughout the cell cycle, some are more effective during the S- and M-phases, making these drugs cell-cycle specific.

Antitumor antibiotic (Cytotoxic antibiotics)

Antitumor antibiotics also called cytotoxic antibiotics are cell cycle nonspecific. They act by binding with DNA and preventing RNA (ribonucleic acid) synthesis, a key step in the creation of proteins, which are necessary for cell survival. They are not the same as antibiotics used to treat bacterial infections. Rather, these drugs cause the strands of genetic material that make up DNA to uncoil, thereby preventing the cell from reproducing.

One of the most important decisions for the oncologist is prescribing the right amount of anti-cancer drugs. Although large doses will kill more cells, greater amounts of drugs will produce more severe side effects. However, lowering the dosage to minimize side effects will also reduce the chances of success. The usual practice is to use the maximum safe dose for effectiveness, even at the cost of temporary side effects. The following section will discuss some common side effects caused by anti-cancer drugs and ways to cope with them.

CHEMOTHERAPY AND MEDICAL GLOVES

POSSIBLE SIDE EFFECTS [20, 21, 22, 23]

Each patient reacts to chemotherapy in a unique way. Some people have very few side effects, while others may experience more. Common side effects of chemotherapy include fatigue, nausea, diarrhea, mouth sores, hair loss, and anemia.

Fatigue is one of the most common side effects of chemotherapy. It may be the result of anemia (a decrease in oxygen-carrying red blood cells), which causes a feeling of lethargy, dizziness, weakness, and shortness of breath. Fatigue may also be a result of a lot of energy being used by the body to recover from the effects of the drugs, disposing of dead cells and building new cells. Other factors, such as pain, poor appetite, lack of rest, and emotional stress may also contribute to a patient's fatigue.

Infection is another side effect some patients experience. Some common signs of infection, such as fever, sore throat, and wounds that do not heal or become inflamed, may occur because the body's capability to fight infection is greatly compromised due to the lowered number of white blood cells. Platelets are important for wound healing and blood clotting. With a low platelet count caused by chemotherapy, the cancer patient is at risk of bruising and bleeding easily. Such side effects as nose bleeds, bleeding gums, blood in the urine or stool, and unusually heavy menstrual flow, may be experienced by the patient receiving chemotherapy.

Nausea and vomiting occur when certain drugs stimulate an area of the brain called the chemoreceptor trigger zone. Overeating, motion sickness, or anxiety can also activate this zone. The effects of some drugs on the fast-growing cells in the lining of the stomach may also cause nausea and vomiting. Diarrhea may be caused from direct damage of the lining of the intestines by some anti-cancer drugs. Anti-nausea drugs may also cause diarrhea.

Hair loss can be extremely devastating to the patient. When chemotherapy agents kill cancer cells, they also kill fast-growing normal cells such as those in hair follicles, causing alopecia (hair loss). In most cases hair, will grow back after chemotherapy is stopped.

Patient and Physician
Source: NCI

Medication may also be prescribed to overcome certain side effects. Since normal cells usually recover when the chemotherapy is over, most side effects should gradually go away once the chemotherapy has ended.

PERSONAL PROTECTIVE EQUIPMENT (PPE) [24]

Chemotherapy drugs are known to be mutagenic (induce or increase genetic mutations by causing changes in DNA; carcinogenic (cancer causing for those exposed to the drug); and teratogenic (causing infertility). Handling of chemotherapy drugs poses potential occupational risks. The occupational risk is highly dependent upon the following criteria:

- Intrinsic toxicity of the chemotherapy drug
- Duration of exposure
- Frequency of exposure
- Drug handling method before, during and after use

According to a 2014 published article "Antineoplastic drug contamination on the hands of employees working throughout the hospital medication system" by C. Hon et.al. [25] and other studies have indicated that occupational exposure to chemotherapy drugs can result in adverse health outcomes including genetic damage, [26, 27] which could lead to cancer, as well as reproductive effects such as miscarriages. [28, 29] The literature indicates that healthcare workers' exposure to chemotherapy drugs is a result of the transfer of surface contamination of these drugs to the skin30 and therefore the primary route of occupational exposure is via dermal contact. [31, 32, 33] Dermal exposure may occur by contacting the drugs directly (i.e. handling manufacturers' vials and/or drug solutions in intravenous bags) or by indirect contact as a result of touching drug-contaminated surfaces.

Therefore, work practice controls are an important part in reducing exposure to hazardous drugs (HDs) and a critical examination of work practices must involve the consistent and appropriate use of engineering controls and personal protective equipment (PPE) to minimize exposure. [34] The use of PPE is one of the most effective ways for healthcare workers to prevent occupational exposure to hazardous drugs. Since standardizing the use of PPE in the healthcare settings, employee exposure to hazardous drugs has decreased. [35] Studies have demonstrated that gloves provide protection against skin contact with tested HDs [36] and preventing skin exposure decreases symptoms in people with occupational contact with HDs. The Oncology Nursing Society defines PPE as chemotherapy tested gloves, gowns made of materials tested for use with chemotherapy, respirators and face shield and goggles. [37]

Gloves tested for handling chemotherapy compounds

Approved chemotherapy gloves should be worn during all hazardous drug handling activities. Gloves offer the first line of protection when handling cytotoxic medicines. The protective qualities of glove material against permeation by a particular cytotoxic agent cannot be determined by data gathered about other agents. Similarly, data about one glove product may not be applied to other products made of similar materials Globally, chemical permeation data is based on three different standards:

- **ASTM D6978-05** 'Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs'
- **ASTM F739-99a** 'Standard Test Method for Resistance of Protective Clothing Materials to Permeation by Liquids, Gases Under Conditions of Continuous Contact'
- **EN (ISO) 374** Protective gloves against dangerous chemicals and micro-organisms

Determination of resistance to permeation by chemicals' EN and ASTM standards exist to ensure that gloves that meet those standards are suitable for their intended use either as medical devices or PPE, providing effective protection for the user and where relevant the patient. It is important to note, that only the ASTM D6978-05 standard is specific to chemotherapy testing and therefore considered the gold standard.[38]

North America [39, 40]

In North America, medical gloves used to handle chemotherapy drugs must fulfill requirements according to the ASTM International (American Society of Testing and Materials) standard D 6978-05. This is the test method recognized by the FDA to obtain 510k certification. In 2005, ASTM developed a standard for testing glove permeability with seven (7) mandatory hazardous drugs from different classifications (Table 1). Two additional hazardous drugs can be selected from a list of 17 drugs provided by the method (Table 2). All drugs are purchased from pharmaceutical drug manufacturers or authorized distributors of pharmaceuticals. Testing is generally conducted at an independent laboratory. Each test drug shall be prepared using the manufacturer's recommended solvent and recognized drug concentration. The gloves are tested at the thinnest section found between the palm and the cuff. They are tested for 4 hours at room temperature. The breakthrough detection time is measured in minutes at which the permeation rate reaches 0.01 µg / cm2 / min.

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Table 1

Compulsory chemotherapy drugs	
Drug	**Concentration (mg/ml)**
Carmustine	3.3
Cyclophosphamide	20.0
Doxorubicin hydrochloride (Adriamycin)	2.0
Etoposide	20.0
Fluorouracil (Adrucil)	50.0
Paclitaxel (Taxol)	6.0
ThioTEPA	10.0

Table 2

Additional chemotherapy drugs (minimum of 2 required)	
Drug	**Concentration (mg/ml)**
Bleomycin sulphate	15.0
Carboplatin	10.0
Cisplatin	1.0
Cytarabine hydrochloride	100.0
Dacarbazine	10.0
Daunorubicin hydrochloride	5.0
Docetaxel	10.0
Gemcitabine	38.0
Idarubicin	1.0
Ifosfamide	50.0
Irinotecan	20.0
Mechlorethamine hydrochloride	1.0
Melphalan	5.0
Methotrexate	25.0
Mitomycin	0.5
Mitoxantrone	2.0
Vincristine sulfate	1.0

EMEA

In the European Union, chemotherapy gloves come under two key directives – the Personal Protective Equipment Directive (PPE) and Medical Devices Directive. Each differs in its remit and delivery, and each one is crucial in its own way. It also means that gloves need to be dual marked as both PPE and Medical gloves.

Personal Protective Equipment Directive (PPE) (Directive 89/686/EEC) [41]

The PPE Directive outlines three categories of design based on the risk their use entails. These are classed as 'simple' (Category-I), 'intermediate' (Category-II) and 'complex design' (Category-III). Each dictates a different level of standards in manufacture and testing.

Manufacturers must provide a detailed technical file outing where products fit within these classifications, how they are designed and produced to adhere to the appropriate classification and any other standards information that applies. Products that have been produced within these strict criteria must also be stamped with the CE mark.

For personal protection against exposure to cytotoxic drugs, use only gloves that are registered as Complex Design (Category III) according to Personal Protective Equipment Directive (89 / 686 / EEC).

Medical Devices Directive [42]

Even more specific to the glove manufacturing industry is the Medical Devices Directive. Any product for medical use in the European market must comply with this directive, which is also used in parallel with the CE mark. The Medical Devices Directive also requires a complex breakdown of different products based on the potential risk in their use, but in a specifically medical context. In the making of medical gloves, manufacturers are bound to go through a strict process of classification of their own products, and end-users make their own assessment of which gloves are most pertinent to their specific line of work.

A set of classifications has been designed to define these various uses and the level of risk each use entails. These are as follows:

Class I – Non-invasive medical devices, including sterile examination gloves

Class IIa – Invasive equipment for short-term use; this includes surgical gloves

Class IIb – Invasive equipment which is usually active and energized

Class III – Critical devices that are used to diagnose, monitor and control of critical internal organs in a body

Within the overall remit of the Medical Devices Directive are several key European Standards, each with more specific guidance on the requirements on manufacturers.

European Standards [43]

The key European Standards which apply to the manufacture of medical gloves includes: EN 420, EN 455, EN 374 and EN 165233-2015.

EN 420 – General Requirements for Protective Gloves [44]

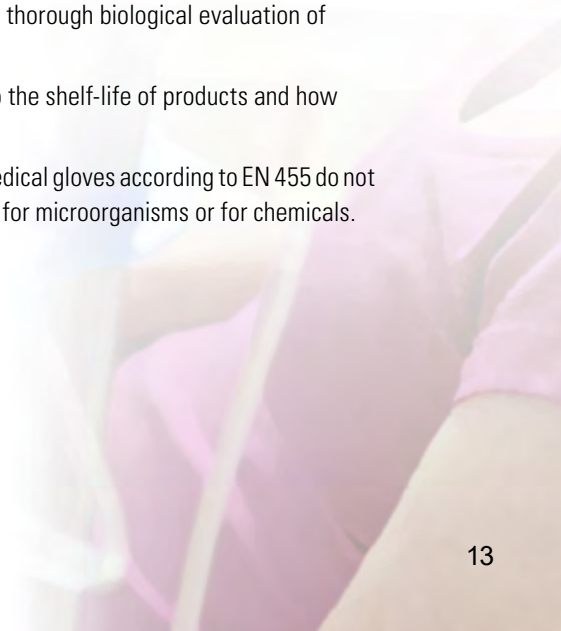
This standard defines the general requirements for glove design and construction, innocuousness, sizing, dexterity, efficiency of production, comfort, or the pictograms and markings that can be used on the glove and packaging.

EN 455 – Medical Gloves for Single Use [45]

The EN455 standard is broken down into four sections:

- **EN 455-1** addresses the requirements on gloves with respect to freedom from holes and how this should be defined and tested (AQL)
- **EN 455-2** covers the physical properties of gloves
- **EN455-3** requires a thorough biological evaluation of products
- **EN 455-4** relates to the shelf-life of products and how well they age

European standards for medical gloves according to EN 455 do not require permeability tests for microorganisms or for chemicals.



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EN (ISO) 374 – Protective Gloves Against Dangerous Chemicals and Microorganisms [46]

EN 374 sets out the required standards for gloves in relation to the handling of the thousands of potentially dangerous chemicals and/or microorganisms protective glove users may encounter in their professional life.

This standard is broken down, into the following sections:

- **EN 374-1:2016** specifies the performance requirements for gloves to protect the user against chemicals and/or microorganisms and defines the terminology to be used;
- **EN 374-2:2014** specifies a test method for the penetration resistance of gloves that protect against chemicals and/or microorganisms. This also relates to the AQL testing methods, namely the water and air retention tests;
- **EN 374-4:2013** addresses the determination of resistance to degradation by chemicals.
- **EN 374-5:2016** addresses terminology and performance requirements for microorganisms.
- **EN 16523-1:2015** addresses determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact.

Asia Pacific

There is no specific regulation that govern the testing of chemo gloves in Australia and other Asia/Pacific countries. In the absence of regulated standards, many of these countries follow the ASTM D6978-05 standard.

GLOVE SELECTION CONSIDERATIONS

CHEMICAL PERMEATION

Chemical permeation is the diffusion of chemicals through intact materials. Many chemicals permeate gloves without visibly affecting the materials and thus gain access to the skin in an insidious manner. If a chemical permeates through the glove, it may cause adverse effects to the skin or it can be absorbed through the skin and cause exposure effects elsewhere in the body. [47] Even normally quite harmless chemicals can damage the skin if the exposure is frequent or prolonged.[48] Furthermore, the inertness of the glove material to the chemical in use is important, because if one chemical degrades the glove material, it can aid in the permeation of other chemicals [49, 50, 51] or microorganisms. [52] It is crucial to be aware that chemical permeation through disposable gloves can sometimes be efficient and rapid. [53, 54, 55, 56]

Permeation involves the following:

1. Adsorption of the molecules of the chemical into the contacted or outer surface of a material.
2. Diffusion of the absorbed molecules in the material.
3. Desorption of the molecules from the opposite or inner surface of the material.

BREAKTHROUGH TIME [57]

The definition of Breakthrough Time is the elapsed time between the initial application of a test chemical and the point in time at which the permeation rate of 0,01 µg/(cm² x min) is detected (ASTM D6978). It is specific for glove material type used in the test. Thinner gloves made from the same material may have a shorter Breakthrough Time. For tasks with inevitable contact, the Breakthrough Time is the maximum time the glove may be used before it should be discarded. If the work lasts for longer than the Breakthrough Time, gloves should be changed part way through. You should allow a safety margin: stretching of gloves during use may mean that breakthrough occurs more quickly than in a test environment. Do not rely on touch to detect breakthrough. Skin exposure will occur long before any perceptible feeling of wetness on the inner surface of the glove. It is important to note that permeation results differ in time and average permeation rate. The risk posed by a chemical permeating a glove is related not just to the speed at which it can diffuse through, but also the flow rate. A combination of a short Breakthrough Time and a low permeation rate may expose a glove wearer to less chemical than a combination of a longer breakthrough time and a much higher breakthrough rate, if the glove is not changed frequently enough.

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CHEMICAL PERMEATION TEST STANDARDS

The following chart outlines testing requirements for chemotherapy certification. [58, 59, 60]

Table 3

Comparison	ASTM D6978-05	ASTM F739	EN16523-1:2015
Test Temperature	35 ° C (+/- 2 ° C)	23 ° C (+/- 1 ° C)	23 ° C (+/- 1 ° C)
Permeation rate	0,01 µg / cm² / min	0,1 µg / cm² / min	1 µg / (cm² x min)
Scope	Determination of resistance to chemotherapy drugs	Determination of resistance to permeation by chemicals	Determination of material resistance to permeation by chemicals. Permeation by liquid chemical under conditions of continuous contact
Test time	240 minutes	480 minutes	480 minutes
Test chemicals	9 cytotoxic drugs – 7 are defined and 2 additional chemicals to be selected by test house	No specific guidance is given on the selection of cytotoxic drugs	3 test specimens to be taken from the palm area. If the glove is longer or equal to 400 mm and if the cuff is claimed to protect against chemical risks, 3 additional test specimens shall be taken where the center is 80 mm from the end of the cuff In the case of seams in the hand area this must be tested
Area of glove that needs to be tested	Palm or cuff whichever is the thinnest part of the glove and outer side of glove (i.e. that which is in contact with chemical)	Palm area for gloves of homogenous design Outer surface to be in contact with chemical	Palm area for gloves of homogenous design Outer surface to be in contact with chemical

GLOVE BEST PRACTICE [61, 62, 63, 64, 65, 66, 67]

As chemotherapy agents remain the treatment of choice for cancer, exposure to cytotoxic drugs in the occupational setting will remain a concern. Healthcare providers at risk are those who are involved with the preparation, handling and administration of chemotherapy drugs. As accumulative exposure to chemotherapy agents may lead to long term toxic effects to the healthcare provider, it is extremely important to ensure the most appropriate personal protective equipment are used and used correctly.

Only gloves approved for use with chemotherapy drugs should be worn. Gloves should meet the EN norms (EN 374 and 455) in Europe and the ASTM (6978-05) standards in the United States. Test standards results should be labeled on the box. Verify permeation time and rate to choose the right glove. Always check the expiry date of gloves prior to use. Expired gloves should not be used.

Gloves should be changed before permeation occurs. Since permeation breakthrough in actual end use may occur sooner than breakthrough under lab test conditions, a margin of safety should be allowed when specifying glove change intervals based on lab data. Always check the material safety data sheet (MSDS) of the cytotoxic drug being used for personal protective equipment requirements.

Powder-free gloves are preferred for handling chemotherapy agents. Powder in gloves may absorb contaminants, be dispersed and increase the potential of surface contamination. OSHA (Occupational Safety and Health Association) 1995 recommended changing gloves every 60 minutes. However, based on permeability testing, the maximum wear time for gloves recommended by the ONS (Oncology Nursing Society) and other professional organizations is 30 minutes. Gloves should be changed if torn, punctured or contaminated. If double gloving, insert first glove under the cuff of the gown and place the second glove over the cuff. If single gloving, place the clean glove over the cuff of the gown.

Before handling chemotherapy drugs, always inspect gloves for holes, tears or any type of defect. Unless the film is intact, it cannot provide a barrier. Although surgical gloves are recommended for preparation, administration, clean up and general handling, sterility is not always required, as for example, direct patient care, handling laundry, and housekeeping procedures. In these situations, chemo approved gloves are available in non-sterile presentations. Gloves not tested for use with hazardous drugs should not be used for handling chemotherapy agents, contaminated linen or waste, due to unknown permeation data.

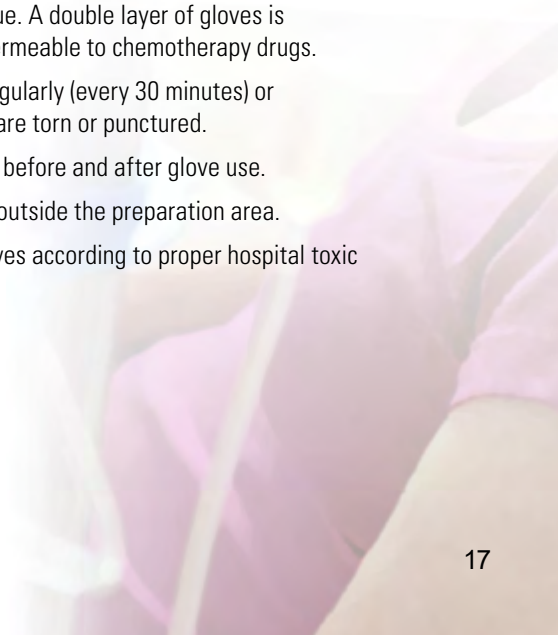
Since the gloves integrity may be affected by ultraviolet radiation, high temperature and ozone, store gloves in a cool dry place away from direct sunlight or ceiling lighting.

General Glove Recommendations

- Always use chemo approved gloves.
- Polyvinyl chloride (PVC) gloves are considered inappropriate because of its generally increased permeability.
- Always use powder-free gloves. Glove powders contaminated with chemotherapy drugs can become airborne and may be subsequently inhaled. Also, powder residue will attach to supplies, work surfaces and the skin.
- If double gloving, insert first glove under the gown cuff and place the second glove over the gown cuff. If single-gloving, place the clean glove over the cuff of the gown.
- Use extra-thick gloves, or better yet, use double gloves.
- Before handling chemotherapy drugs, always inspect gloves for holes, tears or any type of defect. Unless the film is intact, it cannot provide a barrier.
- Although surgical gloves are recommended for preparation, administration, cleanup and general handling, sterility is not always required especially with cleanup and housekeeping procedures.

Drug Preparation

- Always use chemo approved gloves.
- Polyvinyl chloride (PVC) gloves are not recommended for handling chemotherapy drugs.
- Never use powdered gloves during drug preparation.
- Use double gloving unless it interferes with the drug preparation technique. A double layer of gloves is substantially less permeable to chemotherapy drugs.
- Change all gloves regularly (every 30 minutes) or immediately if they are torn or punctured.
- Always wash hands before and after glove use.
- Do not wear gloves outside the preparation area.
- Dispose of used gloves according to proper hospital toxic waste procedures.



CHEMOTHERAPY AND MEDICAL GLOVES

Drug Administration

- Wear chemo approved gloves.
- Double gloving is recommended.
- Wash hands before and after glove use.
- Change contaminated gloves immediately.
- Dispose of gloves according to proper hospital toxic waste procedures.

Drug Clean Up and General Handling

- Wear chemo approved gloves when dealing with blood, vomitus, excreta and other bodily fluids from chemotherapy treated patients.
- Wash hands before and immediately after glove use.
- Discard gloves after each use.
- Laundry personnel encountering linen possibly contaminated with chemotherapy or bodily fluids from a patient undergoing chemo treatment should wear chemo approved gloves.
- Spills should only be cleaned up by personnel wearing a double layer of chemo approved gloves.
- Spill kits for use in responding to spills should include two (2) pair of chemo gloves; one outer pair of utility gloves and one inner pair of latex or latex free gloves.
- All personnel involved in any aspect of handling chemotherapy drugs should receive an orientation on chemotherapy drugs including proper use of protective equipment.

ADDITIONAL PPE RECOMMENDATIONS

Gowns

Gowns that provide adequate protection from chemotherapy agents should be disposable and made of lint-free, low-permeability fabric. They should have a solid front with a back closure with knitted or elastic cuffs. Lab coats are not recommended. The existing guidelines do not dictate wear time of disposable gowns but do recommend changing gowns if contaminated.

Gowns should be used:

- during preparation and administration of chemotherapy drugs;
- disposing of chemotherapy drugs;
- handling patients' blood and bodily fluids.

Eye and Facial Protection

A plastic face shield should be worn in situations where eye, mouth or nasal splashing is possible.

Respiratory Protection

Respiratory protection is necessary when drug aerosols are present or when cleaning up spills. It is important to check the MSDS sheet for recommended respiratory protection when handling compounds

GLOBAL PROCEDURES AND POLICIES

Professional organizations around the globe encourage the use of PPE when compounding, administering and managing chemotherapy treatments.
Table 4 lists several professional organizations and briefly outlines their PPE recommendations.

Table 4 – PPE Recommendations when Handling Chemotherapy Agents

Provider, date, country	Recommendations
ASHP, 2006, US	**Gloves** Gloves must be worn always when handling drug packaging, cartons, and drug vials. (Page 1178) During compounding in a Class II BSC, gloves and gowns are required. (Page 1178) See Appendix C of the ASHP guideline for detailed recommendations. **Gowns** Personal protective gowns are recommended during the handling of hazardous drug preparations. (page 1179) See Appendix D of the ASHP guideline for detailed recommendations. **Other** Eye and face protection should be used whenever there is a possibility of exposure from splashing or uncontrolled aerosolizing of hazardous drugs. A face shield, rather than safety glasses or goggles, is recommended. (Page 1180) Similar circumstances also warrant the use of a respirator. (Page 1180) Shoe and hair coverings should be worn during the sterile compounding process. (Page 1180)
SHPA, 2005, Australia	Protective clothing must be worn by all personnel preparing cytotoxic drugs, cleaning cytotoxic preparation facilities, or cleaning cytotoxic spills. Coveralls are preferable to gowns. Boots or overshoes, head covering, masks and gloves are also compulsory. Safety glasses are strongly recommended for wearers of contact lenses but are otherwise optional. Specific recommendations are provided on page 46 of the SHPA guideline.
NIOSH, 2004, US	Wear PPE (including double gloves and protective gowns) while reconstituting and administering drugs. (Page 13) Detailed recommendations given in NIOSH report.
ONS, 2003, US	**Gloves** Gloves should be worn during all hazardous drug-handling activities. (Page 17) Detailed recommendations are provided on page 18 of the ONS guideline. **Gowns** Gowns that provide adequate protection from hazardous drugs are disposable, made of lint-free, low-permeability fabric. They should have a solid front and knit or elastic cuffs. (Page 18) **Eye and Face Protection** A plastic face shield should be worn in situations where eye, mouth, or nasal splashing or aerosolizing is possible. (Page 19)
HSE, 2003, UK	**Gloves** Where contact with cytotoxic drugs is possible, protective gloves must be provided for employees. (Page 3) **Gowns** Protective clothing such as gowns and aprons can help prevent contamination of clothes and subsequently, the skin. The choice of material is important as their absorptive properties may vary. Standard laboratory coats are unsuitable as cytotoxic drug solutions may soak through them. (Page 3) **Eye and Face Protection** Eye and face protection is relevant, particularly where cytotoxic drugs are being handled outside an enclosed system and where there is a risk of splashing. Several options are available including a face shield or visor, goggles and safety spectacles. (Page 3) **Respiratory protection** If it is not reasonably practicable to control exposure using total enclosure/local exhaust ventilation, you will need to consider respiratory protective equipment (RPE) if exposure to powders or aerosols is possible. Surgical masks will not protect against the inhalation of fine dust or aerosols. (Page 3)

Table 4 – PPE Recommendations when Handling Chemotherapy Agents (continued)

Provider, date, country	Recommendations
Marc, 2003-2005, UK	**Gloves** Always wear gloves when contact with cytotoxic drugs are possible. There is evidence that nitrile and latex gloves offer good protection to the operator from cytotoxic contamination. **Gowns** • Saranex / Tyvek laminated demonstrated to be most effective against 15 antineoplastic drugs. • Laboratory coats are porous – do not use them **Eye and facial protection** Eye protection should fully enclose the eyes, meeting British Standard EN 166. **Respiratory protection** • Surgical masks do not offer protection against aerosols • Appropriate respiratory protection is required wherever total enclosure / local exhaust ventilation cannot control exposure • When solid or liquid particles may be a risk, an FFP2 or FFP3 filtered face piece respirator should be used • For cytotoxic in powdered form, a biological safety cabinet is recommended.
WorkSafe, 2003, Australia	The following personal protective equipment should be provided, in conjunction with other control measures, to personnel who prepare cytotoxic drugs: • coverall or gown • head covering • closed footwear and overshoes • protective gloves – long enough to cover the knitted cuffs of gowns or coveralls • protective eyewear • respiratory protective device (where an inhalation risk exists, for example, a large cytotoxic drug spill). For further information on personal protective equipment, refer to Appendix 9 – Personal Protective Equipment. (Page 21) Using the following personal protective equipment is recommended during the administration of cytotoxic drugs (where there is an assessed exposure risk): • gown • closed footwear • protective gloves • protective eyewear (where there is a risk of eye splash) • respiratory protective device (where an inhalation risk exists, for example, after a large cytotoxic drug spill). (Page 23)
DGOP, 2003, Germany	• The directives, regulations and guidelines currently in force stipulate the use of protective equipment by every employee of a cytostatic department deriving from evaluation of the hazards involved. In the case of cytostatic preparation, this also applies to those employees who put together the finished drugs for the preparation and package the ready-to-administer solutions. • Personal protective equipment includes: • overall or protective gown (possibly in combination with cuffs) • protective gloves • and in special cases » respiratory protective equipment » protective eyewear » overshoes. (Page 58) • Very detailed descriptions appear on pages 63-86 of the DGOP guideline.

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REVIEW

We learned that for some cancers, chemotherapy alone can destroy all the cancer cells and cure the cancer (primary treatment). That all cells, healthy and malignant, go through distinct phases in their life cycle – called the cell cycle. Chemotherapy drugs are designed to disrupt a cell's function at one or all of these phases. It is also important to know that normal cells, as well as cancer cells, are affected by chemotherapy, and the cause of unpleasant side effects is toxicity of the drugs to normal cells.

Chemotherapy can be used for curative and palliative purposes and it is often given after other therapies (such as surgery or radiation) have destroyed the clinically detectable cancer cells (adjuvant chemotherapy). In the discussion of chemotherapy drugs, we learned that there are different ways that chemotherapeutic agents are administered: oral chemotherapy; intravenous chemotherapy; and intrathecal and intraperitoneal chemotherapy.

In addition, the major categories of chemotherapy agents were described: alkylating agents; antimetabolites; plant alkaloids; and anti-tumor antibiotics. Some side effects caused by chemotherapy include fatigue, nausea, diarrhea, hair loss, and changes in mood and emotions.

We also learned that handling of chemotherapy drugs poses potential occupational risks and that certified personal protective equipment such as gloves, gowns and respiratory protection are required.

GLOSSARY

ANEMIA
A reduction in total circulating red blood cell mass, diagnosed by a decrease in hemoglobin concentration. Anemic patients have low oxygen-carrying capacity of the blood, with resultant tissue hypoxia. The clinical symptoms are related to the severity of the anemia, and may include pallor, tachycardia, angina, lightheadedness and fatigue. Anemia may be due to increased blood loss, decreased red blood cell production, or increased red blood cell destruction.

ANTI-CANCER DRUGS
Or antineoplastic drugs – used to eradicate or control the growth of cancer.

ASHP
The American Society of Health-System Pharmacists.
http://www.ashp.org/

ASTM INTERNATIONAL
Standards Worldwide; originally founded as American Society for Testing Materials. https://www.astm.org/

CELL DIVISION
The process by which cells reproduce (mitosis). The cell cycle is a series of changes the cell goes through from the time it is first formed until it divides into two daughter cells.

CYTOTOXIC DRUGS
Agents with anti-cancer properties that may also damage cancer cells.

DIARRHEA
Frequent, loose, and watery bowel movements; common causes include gastrointestinal infections, irritable bowel syndrome, medicines, and malabsorption.

DNA
A double-stranded helix of nucleotides which carries the genetic information of a cell. It encodes the information for the proteins and can self-replicate.

GAMMA RADIATION
A highly energized, deeply penetrating photon that radiates from the nucleus during fission and frequently accompanies radioactive decay.

DGOP
Stands for Deutsche Gesellschaft für Onkologische Pharmazie (German Society for Oncology Pharmacy). http://dgop.org/

HSE
Health and Safety Executive. http://www.hse.gov.uk/

INNOCUOUSNESS
Not likely to harm or cause injury to someone.

LEUKEMIA
A malignant proliferation of hematopoietic cells, characterized by replacement of bone marrow by neoplastic cells. The leukemic cells usually are present in peripheral blood, and may infiltrate other organs of the reticuloendothelial system, such as liver, spleen and lymph nodes. Leukemia is broadly classified into acute and chronic leukemia, with multiple distinct clinic-pathologic entities sub in each category.

MARC
Management and Awareness of the Risks of Cytotoxics.
https://pearl.plymouth.ac.uk/handle/10026.1/3732

MITOSIS
A complex process which allows the cell to give identical copies of its DNA to each of the daughter cells.

MOLECULES
The smallest unit of matter of a substance that retains all the physical and chemical properties of that substance, consisting of a single atom or a group of atoms bonded together; e.g.,
Ne, H2, H2O.

M-PHASE
The cell cycle phase during which nuclear division occurs, and which is comprises the phases: prophase, metaphase, anaphase and telophase and occurs as part of a mitotic cell cycle.

NIOSH
National Institute for Occupational Safety and Health.
http://www.cdc.gov/niosh/

ONS
Oncology Nursing Society. https://www.ons.org/

PLATELETS
Particles found in the bloodstream that binds at the site of a wound to begin the blood clotting process. Platelets are formed in bone marrow.

SHPA
Society of Hospital Pharmacy Australia.
http://www.shpa.org.au/

S-PHASE (SYNTHESIS PHASE)
The part of the cell cycle in which DNA is replicated, occurring between G1 phase and G2 phase. Precise and accurate DNA replication is necessary to prevent genetic abnormalities which often lead to cell death or disease.

WORKSAFE VICTORIA
A government workplace safety program.
http://www.worksafe.vic.gov.au/

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