

DIPARTIMENTO DI  
MEDICINA VETERINARIA



**Ospedale Didattico Veterinario**

**BIOSECURITY MANUAL OF ONCOLOGY UNIT**

Rev.	Data	Descrizione

## Introduction:

The purpose of this manual is to define the risks and procedures aimed at ensuring the safety of the structured personnel of DiMeV during the administration of chemotherapy to oncology patients. This manual is valid in the Veterinary Teaching Hospital (ODV) and in the chemotherapy room where practical and internship activities are carried out. This manual is based on the guidelines published by the American College of Veterinary Internal Medicine (ACVIM) in the Journal of Veterinary Internal Medicine in 2018 (DOI: 10.1111/jvim.15077).

## General Information:

The access of oncology patients is conditioned by the adoption of appropriate measures to guarantee the biosafety of the personnel and the environments (for specific details, refer to the ODV biosafety manual). Access to the chemotherapy room is allowed only to ODV personnel (doctors, technicians, and students); pregnant women and immunocompromised individuals are prohibited from entering.

## Objectives:

To provide correct access methods for authorized personnel, correct storage, preparation/reconstitution, administration, and disposal procedures for antineoplastic substances. The procedures aim to establish necessary safety measures for handling such substances through appropriate caution and correct disposal using suitable personal and collective protective equipment (PPE; CPE) and devices. PPE and CPE to be used:

It is mandatory to wear appropriate attire for ambulatory activities: lab coat, scrub, and suitable footwear. For body, hand, mouth, and eye protection during preparation and administration of antineoplastic drugs, the following PPE is necessary: polypropylene lab coat, disposable nitrile gloves, face shield or goggles, mask. Students are not allowed to reconstitute or manipulate antineoplastic drugs, but they are permitted to assist veterinary personnel in their administration. At the end of activities, all disposable PPE (gloves, lab coats) will be disposed of in appropriate containers. Everyone in the room must wash their hands and apply hand sanitizer using the provided dispenser. CPE: Class I filtration hood. Authorized personnel and access regulation:

Access to the chemotherapy room is allowed for all medical personnel affiliated with ODV, technical personnel, trainees, graduate students, research fellows/assistants, interns, authorized by the Health Director/Department Director. During the preparation/reconstitution and administration of antineoplastic drugs, access is prohibited for:

- Personnel not involved in oncology activities.
- Unauthorized students.
- Pregnant or presumed pregnant women, breastfeeding women.
- Minors, even if accompanied by parents/legal guardians.
- Technical-administrative staff, structured and non-structured veterinary medical personnel without tasks to be performed in the chemotherapy area.
- Unauthorized animal owners or those who have not been informed of the regulations and safety rules governing access to the chemotherapy room.

During the administration of antineoplastic drugs, access is allowed for:

- Veterinary medical personnel responsible for administering antineoplastic drugs, using all necessary personal protective equipment (PPE Category III according to Directive 86/686/EEC adopted in Italy by Legislative Decree 475 of 4/12/92 and attachments) in sufficient numbers and at the discretion of the responsible person, in order to guarantee the lowest possible risk for both the patient and the staff present. The veterinary medical personnel in charge of administering antineoplastic drugs must undergo an annual

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examination by a competent physician, in accordance with the individual occupational destination sheet.

- Authorized trainees and graduate students who have no active role during the administration and who are properly equipped with protective lab coats (PPE Category III according to Directive 86/686/EEC).
- Owners of patients, to facilitate their management, provided they are equipped with protective lab coats and shoe covers and have been informed of the risks and regulations governing access to the chemotherapy room. General Behavioral Guidelines:

The access door to the chemotherapy clinic must be clearly identified with signs stating: "Access forbidden for unauthorized personnel" and "Biological and chemical risk zone." Consuming food and beverages, smoking, applying makeup, and handling contact lenses are prohibited inside the clinic. The PPE used in the chemotherapy clinic should be reserved for the preparation, administration, storage, and disposal of antineoplastic drugs. Disposable polypropylene lab coats and gloves must be worn in the clinic and disposed of in appropriate containers at the end of procedures. Handling common-use objects (phones, computers, pens, etc.) with potentially contaminated gloves is prohibited. Handwashing with soap and water must be performed immediately after handling chemotherapy substances and always after completing procedures. Maintain cleanliness of surfaces inside the clinic, especially between procedures. Needles and other sharp objects must be handled with care and disposed of in appropriate containers. Reconstitution of antineoplastic drugs must be done under the hood exclusively by authorized medical personnel, following the procedures specified for each drug, and using only Category III PPE. The chemotherapy room always has an emergency kit for managing accidental spills of antineoplastic drugs (PPE Category III according to Directive 86/686/EEC). Unused portions of drugs, as indicated by the manufacturer's package insert, must be properly stored or disposed of if storage is not possible.

#### Handling of Chemotherapeutic Drugs:

The chemotherapeutic drugs will be stored in a refrigerator equipped with a lock and temperature control/monitoring if they need to be refrigerated. Drugs kept at room temperature will be stored in a dedicated cabinet with a lock, located in the same room.

#### Administration of Intravenous Chemotherapy in the Chemotherapy Room:

Ensure adequate containment of the patient by an operator experienced in extravasation procedures (or ensure that another person with such experience is present in the room). If necessary, lock the door of the unit to avoid interruptions. Follow the protocols for chemotherapy administration as indicated by the responsible physician.

#### Administration of Chemotherapy Outside the Oncology Unit (Ward, Surgery, Intensive Care):

Carefully consider on a case-by-case basis before administering chemotherapy outside the chemotherapy room and proceed only if necessary. Check with a staff member from the relevant area before proceeding. Pack the necessary items in a bag for safe transport of antineoplastic drugs to the selected area. Bring two chemotherapy absorbent mats (one under the patient, one in case of spills). Use "cytotoxic risk" warning signs, which will be applied to the cage of the patient undergoing infusion chemotherapy.

#### Administration of Electrochemotherapy in the Oncology or Surgery Room:

After reconstituting the antineoplastic drug under the hood and if it is necessary to perform electrochemotherapy in the surgery room, store the reconstituted drug in a syringe inside a bag for transporting antineoplastic drugs. Place the electroporator on a flat, safe surface. Ensure that the sharp electrodes are adequately protected to prevent accidental injuries. Students are not authorized to use the equipment. In case of electroporation near the endotracheal tube (nose, oral cavity), interrupt oxygen inhalation to avoid combustion.

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Manipulated Drugs:

Antimetabolites:

- Cytarabine

Antimicrotubule agents:

- Vincristine
- Vinblastine
- Vinorelbine

Antitumor antibiotics:

- Bleomycin
- Dactinomycin

Anthracyclines and anthracycline analogs:

- Doxorubicin
- Mitoxantrone

Platinum salts:

- Carboplatin
- Cisplatin

PPE: gloves, goggles, mask, and lab coat CPE: hood, safety means (vial adaptor), sodium hypochlorite, sawdust, bags for disposal of expired or empty drugs

Specific Manipulation of Drugs:

1. Vincristine: Store in the refrigerator for a maximum of 24 hours, protected from light, manipulated under the hood, using LUER-LOCK syringes. CONTACT: If in contact with the skin, wash abundantly with soap and water; if in contact with eyes, wash for 15 minutes. IN CASE OF SPILL: Wear 2 pairs of gloves, respiratory mask, protective lab coat, and goggles. Use absorbent materials such as paper, sawdust, or absorbent gravel, 5% sodium hydroxide solution. Collect everything in plastic containers. Clean the surface with water.
2. Vinblastine: Same as Vincristine.
3. Bleomycin: Store in the refrigerator for a maximum of 10 days, at room temperature for 24 hours. No particular precautions for manipulation.
4. Doxorubicin: Store in the refrigerator for a maximum of 24 hours, protected from light, manipulated, using LUER-LOCK syringes. CONTACT: If in contact with the skin, wash abundantly with soap and water; if in contact with eyes, wash for 15 minutes. IN CASE OF SPILL: Wear 2 pairs of gloves, protective lab coat, and goggles. Use absorbent materials such as paper, 1% sodium hypochlorite solution. Collect everything in plastic containers. Clean the surface with water and soap twice.
5. Mitoxantrone: Store in the refrigerator for a maximum of 24 hours, protected from light, manipulated, using LUER-LOCK syringes. CONTACT: If in contact with the skin, wash abundantly with soap and water; if in contact with eyes, wash for 15 minutes. IN CASE OF SPILL: Wear 2 pairs of gloves, protective lab coat, and goggles. Use absorbent materials such as paper, calcium hypochlorite solution (5.5 parts in 13 parts of water). Collect everything in plastic containers. Clean the surface with water and soap twice.
6. Carboplatin and Cisplatin: Store in the refrigerator for a maximum of 24 hours, protected from light, manipulated under the hood, using LUER-LOCK syringes. CONTACT: If in contact with

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the skin, wash abundantly with soap and water; if in contact with eyes, wash for 15 minutes.  
IN CASE OF SPILL: Wear 2 pairs of gloves, protective lab coat, and goggles. Use absorbent materials such as paper, sawdust, or absorbent gravel, sodium hypochlorite solution. Collect everything in plastic containers. Clean the surface with water.

#### SOP: CHEMOTHERAPEUTIC EXTRAVASATION PROCEDURES:

1. Vesicant Drugs: Vincristine, Vinblastine, Doxorubicin, Epirubicin.
2. Vesicant Agents: Cisplatin, Mitoxantrone.
3. Irritant Drugs: Carboplatin.

#### TO DO LIST IN CASE OF EXTRAVASATION:

- Stop the infusion.
- DO NOT REMOVE the intravenous catheter.
- Try to ASPIRATE the drug.
- Administer Dexrazoxane (0.15 mg/kg IV) through the placement of a new catheter on another limb (unless contraindicated, for example, if the patient is on NSAIDs).
- Apply ointments containing fusidic acid to the extravasation site.
- Inform the supervisors.

#### SPECIFIC RECOMMENDATIONS:

1. VINCRISTINE/VINBLASTINE:
  - Inject 5-15 ml of 0.9% NaCl through the catheter and into the subcutaneous area around the extravasation site and then attempt aspiration.
  - Infiltrate 1500 units of Hyaluronidase into the extravasation area.
  - Apply warm and compressive dressings for 3-4 hours following the extravasation.
2. DOXORUBICIN/EPIRUBICIN:
  - Administer Dexrazoxane by slow IV bolus within 3 hours of extravasation (ratio 10:1; i.e., 300 mg/m<sup>2</sup> of Dexrazoxane to 30 mg/m<sup>2</sup> of Doxorubicin). The dose can be repeated at 24 and 48 hours after extravasation.
  - If Dexrazoxane is not available, infiltrate the extravasation area with 2-5 ml of 3% Sodium Bicarbonate and then aspirate (dilute 50% sodium bicarbonate at a 1:4 ratio to achieve 2.1% solution. Note that sodium bicarbonate is an irritant).
  - Additionally, if Dexrazoxane is not available, apply DMSO to the extravasation area every 2 hours, wearing gloves.
  - Apply topical applications of fusidic acid.
  - Apply cold dressings for 6-10 hours following extravasation.
3. CISPLATIN:
  - Inject 5-15 ml of 0.9% NaCl through the catheter and into the subcutaneous area around the extravasation site and then attempt aspiration.
  - Infiltrate 1500 units of Hyaluronidase into the extravasation area.
  - If available, infiltrate the extravasation area with 2-5 ml of 3% Sodium Thiosulfate and then aspirate (3% Sodium Thiosulfate is obtained by diluting 1.2 ml of 50% solution in 20 ml of API).
  - Apply warm and compressive dressings for 3-4 hours following extravasation.